

# Washington State Patrol

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## BREATH TEST PROGRAM

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### Technical Manual

Revision November 2017

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Impaired Driving Section  
Forensic Laboratory Services Bureau  
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Seattle, WA 98102

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# 1 TECHNICAL SERVICES PROGRAM

This manual describes the Technical Services Program of the Washington State Patrol's (WSP) Breath Test Program as it relates to its breath alcohol calibration functions.

The Toxicology Laboratory Division (TLD) and the Breath Test Program (BTP) are both responsible for the breath alcohol calibration functions of the Forensic Laboratory Services Bureau (FLSB). The TLD prepares and certifies two types of simulator solutions: the Quality Assurance Procedure (QAP) solutions and the External Standard Solution. These solutions are then used by the BTP, where the QAP solutions are used to set and confirm the adjustment of the evidentiary breath test instruments. The External Standard Solution is used to verify the accuracy and proper working order of the DataMaster and DataMaster CDM instruments as part of a field evidential breath test. Simulator solutions may also be ordered from approved external vendors. For the Draeger Alcotest 9510 instruments (Draeger), a certified ethanol dry gas standard is used to verify the accuracy and proper working order of these instruments as part of a field evidential breath test.

Unless otherwise indicated, "DataMaster" refers to both the DataMaster and the DataMaster CDM in this manual. Unless otherwise indicated, the Draeger Alcotest 9510 may be referred to here or in other manuals as the Draeger, Dräger, Drager, 9510 or Alcotest 9510.

The purpose of this manual is to specify in detail the many policies and procedures that shall be followed in order for the BTP to fulfill its breath alcohol calibration responsibilities.

The official version of this manual is the electronic version as it appears on the FLSB SharePoint site (FLSB Portal). This manual covers all work done by responsible personnel, to include but not limited to work done in the individual calibration laboratories within the BTP, in addition to duties outside the laboratory, whether in court, training venues, or anywhere else the duties of responsible personnel might be employed.

## 1.1 POLICY

The BTP shall document its policies and procedures to the extent necessary to assure the quality of the calibration results. Compliance with pre-established and carefully designed policies and procedures is important to ensure the work product and services are accurate and fit-for-purpose. The policies and procedures outlined in this manual shall be communicated to, available to, understood by, and implemented by the responsible personnel.

All calibration and related services performed by the BTP shall meet generally recognized standards of the forensic community and its accrediting organizations. Specifically, the BTP shall perform all calibration activities in accordance with the specified program policies and the ISO 17025:2005 accreditation standards.

All employees are required to familiarize themselves with this manual and implement the policies and procedures specified herein. In doing so, the BTP will maintain the highest level of expertise and analytical confidence for the criminal justice system and comply with the ISO 17025:2005 accreditation standards and ANAB supplemental standards.

Any adjustments or deviations from the policies and procedures detailed in this manual must be approved by the Impaired Driving Section (IDS) Commander, the Manager of the Standards and Accountability Section (SAS), and/or the State Toxicologist, and appropriately documented in the Instrument Record.

## **1.2 DEFINITIONS**

### **1.2.1 ACCURACY**

The proximity of a measured value to a reference value.

### **1.2.2 ADJUSTMENT**

The process by which known traceable standard(s) having reference value(s) are introduced into an instrument. The instrument is then adjusted or programmed (either by software, hardware, electronics, etc.) to report a measurement based on the known reference value(s).

### **1.2.3 ANAB**

ANSI-ASQ National Accreditation Board (ANAB) is an organization that accredits forensic science calibration laboratories to ISO/IEC 17025 standards and the ANAB ISO/IEC 17025 – Forensic Science Calibration Laboratories Accreditation Requirements.

### **1.2.4 BACK-UP TECHNICIANS**

Personnel who are fully trained and certified as Breath Test Technicians. Their assignments, however, are typically in the WSP Field Operations Bureau. They will assist the local full-time Breath Test Technician, as required.

### **1.2.5 BIAS**

The difference between a measurement result and the true reference value of the property being measured. The bias quantifies the accuracy of the measurement.

### **1.2.6 BREATH TEST TECHNICIANS / TECHNICIANS**

Currently qualified Operators who are trained and certified in the following areas of responsibility: instrument calibration, certification, repair, maintenance, documentation, training of operators and expert court testimony. Technicians are also qualified as Instructors, Preliminary Breath Test Technicians and External Standard Changers.

### **1.2.7 CALIBRATION**

The process where a range of simulator solutions with different concentrations are tested to ensure that their values satisfy the requirements for precision and accuracy. Previously known as linearity checks.

### **1.2.8 CALIBRATION CERTIFICATE**

The final result sheet produced at the end of the process of calibrating a breath test instrument, known herein as the Quality Assurance Procedure (QAP).

### **1.2.9 CALIBRATION FILE**

Refers to documents kept as part of the QAP File.

#### 1.2.10 CALIBRATION RECORDS

Refers to documents kept as part of the Instrument Record.

#### 1.2.11 CERTIFICATE OF ANALYSIS (COA)

Documentation provided by the manufacturer of ethanol dry gas standards which states the tested concentration of the gas, analytical accuracy of the reported value, and traceability.

#### 1.2.12 COEFFICIENT OF VARIATION (CV)

The relative standard deviation expressed as a percentage of the mean.

#### 1.2.13 COMBINED UNCERTAINTY

The estimate of measurement uncertainty that includes the contribution from all components significantly influencing a measurement result

#### 1.2.14 EVIDENTIARY BREATH TEST INSTRUMENT

An instrument approved by the State Toxicologist that is calibrated and verified for measuring breath alcohol content. The instruments approved for the state of Washington are the DataMaster, the DataMaster CDM, and the Draeger Alcotest 9510.

#### 1.2.15 EXTERNAL STANDARD

The reference standard attached to the instrument and used to provide a known alcohol vapor concentration to verify the accuracy and proper working order of the instrument as part of a field evidentiary breath test. This can be either an ethanol/water solution (External Standard Solution) or a dry gas (Dry Gas External Standard) consisting of an ethanol/nitrogen mixture.

#### 1.2.16 EXTERNAL STANDARD CHANGERS

Currently qualified Operators who are trained and certified to change the external standards located with each breath test instrument.

#### 1.2.17 INSTRUCTORS

Personnel that are currently qualified Operators and additionally trained and certified to have the responsibility for training other Operators on the use of the breath test instruments.

#### 1.2.18 INSTRUMENT RECORD

All records and documentation related to a specific breath test instrument. In addition to the QAP file, records may include maintenance files, status sheets, solution change records, instrument printouts, etc.

#### 1.2.19 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST)

A federal agency located within the Department of Commerce with final authority for metrology in the United States.

#### 1.2.20 OPERATORS

Personnel trained and certified to be Operators of the evidentiary breath test instruments. This includes most law enforcement officers within the state.

#### 1.2.21 PRECISION

The ability of a technique to perform a measurement in a reproducible manner. Precision is quantified by the standard deviation.

#### 1.2.22 PRELIMINARY BREATH TEST (PBT) INSTRUMENT

A handheld breath alcohol screening device that includes both the Alco-Sensor FST and Alco-Sensor III instruments. These instruments are approved by the State Toxicologist and are used by law enforcement officers at the roadside to measure breath alcohol and help establish probable cause for arrest.

#### 1.2.23 QUALITY ASSURANCE PROCEDURE (QAP)

A testing procedure for evidentiary breath test instruments in which known traceable reference materials are used to set and confirm the adjustment and establish quantitative estimates for bias and precision. Several other performance measures are also evaluated in order to ensure the proper working order and evidential suitability of the instrument.

#### 1.2.24 QUALITY ASSURANCE PROCEDURE FILE (QAP FILE)

A file containing all documentation produced as a result of the QAP process. Documents include the QAP Worksheet, the DataMaster Calibration Certificate or the Draeger Alcotest 9510 Calibration Certificate, any printouts produced by the instrument, and the QAP Review Form.

#### 1.2.25 QUALITY ASSURANCE PROCEDURE SOLUTION (QAP SOLUTION)

The solution used within the simulator to provide a known alcohol vapor concentration to set and confirm the adjustment of the evidentiary breath test instrument.

#### 1.2.26 QUALITY ASSURANCE (QA) MANAGER

Operationally, the FLSB Standards and Accountability Manager.

#### 1.2.27 ROUNDING

When rounding is performed for computational purposes, normal rules of rounding are followed unless otherwise specified.

#### 1.2.28 SIMULATOR

A device, when filled with a certified simulator solution maintained at a known temperature, that provides a vapor sample of a known ethanol concentration.

#### 1.2.29 SOLUTION TEST REPORT

The final result sheet produced at the end of either a QAP solution or the External Standard Solution testing process. It includes ethanol concentrations from individual solution aliquots, ethanol control results, statistical data, signatures of the preparer and other certifying analysts, and dates of preparation testing and issuance.

#### 1.2.30 STANDARD UNCERTAINTY

The uncertainty of a measurement result expressed as a standard deviation.



#### 1.2.31 TRACEABILITY

The property of a measurement result whereby it can be related to standard references, usually national or international, through an unbroken chain of comparisons all having stated uncertainties.

#### 1.2.32 UNCERTAINTY / MEASUREMENT UNCERTAINTY

A parameter, associated with a measurement result that characterizes the dispersion of the values that could reasonably be attributed to the true value being measured.

## **2 RECEIPT AND STORAGE OF SIMULATOR SOLUTIONS AND DRY GAS STANDARDS**

### **2.1 POLICY**

Each QAP and External Standard Solution (ESS) is prepared and certified by authorized personnel within the TLD prior to their distribution to breath test technicians. Alternatively, certified simulator solutions may be ordered from an approved vendor. On receipt of simulator solutions, the Technician must verify and inspect the order, document receipt, and store the solutions appropriately.

Certified Dry Gas External Standards shall be ordered from an approved vendor. On receipt of Dry Gas External Standards, the Technician must verify and inspect the order for correct ethanol concentration and quantity ordered, document receipt of the shipment, and store the canisters appropriately.

### **2.2 PROCEDURE**

2.2.1 On receipt of the simulator solutions, the Technician shall sign and date the packing slip, indicating:

- Verification of order – adequate amount, correct concentrations, etc.
- Inspection of bottles – no damage, leaking, broken seals, etc.
- Appropriate Test Report(s) included
- Record of receipt

2.2.2 Once receipt has been verified the person receiving the shipment shall notify BTP headquarters and forward the completed packing slip.

2.2.3 On receipt of the Dry Gas External Standard, the Technician will sign and date the packing slip, indicating:

- Verification of order – adequate amount, correct concentrations, etc.
- Inspection of canisters – no damage, leaking, broken valves, etc.
- Appropriate Certificate(s) of Analysis included
- Record of receipt

2.2.4 Once receipt has been verified the person receiving the shipment shall notify BTP headquarters and forward the completed packing slip.

- 2.2.5 If any discrepancies are noted, the Technician should contact the TLD, approved simulator solution vendor, or the dry gas provider. Discrepancies may include insufficient quantity of the standards, incorrect concentration, damaged and/or leaking bottles or canisters, and broken seals or valves. Any discrepancies and subsequent resolution will be documented on Solution Request/Packing Slip or the dry gas manufacturer packing slip.
- 2.2.6 On receipt of the standards, the Technician should store them in a secure cabinet/closet separate from any volatile chemicals. Extreme temperature should be avoided.
- 2.2.7 A laboratory may receive an amount of dry gas cylinders that exceeds the locked cabinet storage capacity. Technicians at these laboratories are authorized to secure the cylinders outside of locked storage cabinets with the following restrictions:
- Cylinders must be kept in the laboratory.
  - The laboratory must be locked when the Technician is not present.
  - Cylinders shall be checked for tampering prior to use.
  - Cylinders must be stored away from heat sources, volatile chemicals, and impact/puncture hazards.
- 2.2.8 The QAP and External Standard Solutions prepared and certified by authorized personnel within the TLD are valid and approved for use for a period of one year from the date of preparation. Expired solutions may be discarded down a drain with additional water, and the solution containers discarded in the trash or recycled. If expired solutions are retained for training purposes then each container must bear identification that reads similar to "Training Purposes Only" and be stored separate from non-expired QAP and External Standard Solutions.
- 2.2.9 Dry Gas External Standards are valid for use for a period of three years from the date of certification. The canisters are clearly labeled with expiration date and lot number. Standards that have expired shall be discarded by removing the pressure pin and releasing the remaining pressurized gas into the atmosphere. If expired standards are retained for training purposes then each canister must bear identification that reads similar to "Training Purposes Only". These shall be stored separate from non-expired dry gas standards.
- 2.2.10 When a QAP solution is transferred to a simulator, the simulator is to be labeled with the identity of the QAP solution, the QAP solution batch number and the in service date.
- 2.2.11 If solutions or dry gas standards need to be transported to sites other than a permanent laboratory facility, care shall be taken to protect their integrity and avoid damage, leakages and extreme heat.

### **3 DATAMASTER QUALITY ASSURANCE PROCEDURE**

The DataMaster Quality Assurance Procedure (QAP) ensures the accuracy, precision and forensic acceptability of the DataMaster breath test instrument for the purpose of quantitative evidential measurement of the alcohol concentration of a person's breath. The procedure evaluates critical systems within the instrument to ensure their compliance with strict predetermined criteria. When complying with the standards required in the QAP, the DataMaster can be confidently placed in the field for evidential use.

When the QAP is undertaken at sites other than a permanent laboratory facility, the location should provide moderate environmental conditions of temperature and humidity as commonly found under normal laboratory conditions. Calibration shall be stopped if the Technician determines that environmental conditions in any calibration location jeopardize the results of the calibration. The transportation, handling and storage of instruments being calibrated shall be done in such a way as to protect the integrity of the instrument. While undergoing transport and whenever stored in a permanent laboratory facility, the instruments will be treated with the care deserving of a precision measurement device and any storage both before and after conducting the QAP will be in a secure, limited-access location.

For any equipment requiring transportation to sites other than the permanent laboratory facility, the transportation and handling shall be done in such a way as to protect the integrity of the equipment.

When documenting the calibration item and/or equipment used, the serial number shall act as the unique identifier, unless otherwise noted.

#### **3.1 CONDITIONS REQUIRING THE QAP**

The procedure described below is to be followed when performing the QAP on DataMaster instruments. This procedure shall be completed in the following circumstances:

- Prior to an instrument being installed initially in the field for evidentiary use.
- After replacing any of the following components and prior to being placed back into the field for evidentiary use:
  1. Central Processing Unit (CPU) Board
  2. Infrared Detector
  3. Infrared Detector Block
  4. Infrared Detector Board
  5. Software
  6. Replacement of Infrared Lamp
- After disassembly and then reassembly of sample chamber.

- If instrument requires recalibration for any reason.
- At least once every 12 months.

3.1.1 If an instrument has had a current QAP performed and is in spare status, it does not need another QAP if deployed in evidential mode.

### **3.2 DATAMASTER INSTRUMENT ASSESSMENT**

Prior to performing the QAP, the “As Found” performance of the DataMaster shall be assessed. The assessment may be conducted at the installation site or laboratory. A single supervisory test (SUP) shall be performed using a certified 0.08 simulator solution. The keyboard will be on and the Technician will enter their name. The resulting breath test document will be retained in the QAP file and the acceptability of the assessment will be indicated by checking the appropriate section of the QAP Worksheet and entering the “As Found” result on the DataMaster Calibration Certificate. Acceptability is defined as an “As Found” result between 0.072 and 0.088, inclusive. In the event that the assessment indicates an unacceptable result, the QAP procedure is immediately halted and a supervisor is contacted.

The intention of the “As Found” is to show the condition or working order of the instrument before being adjusted. Therefore, if a successful “As Found” test is obtained those results are to be recorded on the required documents. If a “Repair” is needed and no “As Found” results can be obtained the “As Found” test will not be applicable. Similarly, if the instrument was not previously calibrated within the timelines set forth in this chapter, the test will not be applicable.

If the QAP is being conducted following any repair or replacement of components which would make instrument assessment impossible, then this section does not apply.

### **3.3 PROCEDURE**

The following shall be conducted by the Breath Test Technician performing the calibration. This procedure shall be performed when the instrument is fully warm. While conducting the following procedure, the Technician shall complete the QAP Worksheet. If at any point throughout the QAP procedure it becomes necessary to begin the entire QAP again, all of the paperwork up to that point shall be retained while noting the reason on the QAP Worksheet. The reason for restarting the QAP shall be noted on the worksheet under the “QAP not acceptable” comments section.

#### **3.3.1 ELECTRICAL CHECKS**

##### **3.3.1.1 Sample Chamber Control Board Version #101226**

###### **A. Flow Detector**

1. Place black voltmeter lead on Test Point (TP)5
2. Place red voltmeter lead on bottom of R28
3. Adjust R26 to 0.200 ( $\pm 0.005$ ) Volts Direct Current (VDC)
4. Move red lead to TP2
5. Adjust R29 to 1.40 ( $\pm 0.10$ ) VDC

6. Move red lead back to bottom of R28
7. Adjust R26 to 0.020 ( $\pm 0.010$ ) VDC
8. Sample Threshold
9. Leave black voltmeter lead on TP5
10. Place red voltmeter lead on TP1
11. Adjust R34 to 2.40 ( $\pm 0.10$ ) VDC

B. Sample Chamber Control Board Version #41625

1. Breath Volume Circuit Place black voltmeter lead on TP5
2. Place red voltmeter lead on TP8
3. Adjust R26 to 0.200 ( $\pm 0.005$ ) VDC
4. Move red lead to TP2
5. Adjust R29 for 1.40 ( $\pm 0.10$ ) VDC
6. Move red lead back to TP8
7. Adjust R26 to 0.020 ( $\pm 0.010$ ) VDC

3.3.1.2 Detector Board: (TP4 is ground)

A. Infrared (IR) Detector Cooler (DetClr):

1. TP1: Adjust R4 to voltage indicated on tag attached to cable coming from J37 on Detector Board ( $\pm 0.01$ ) VDC.
2. If the tag listing the cooler voltage is not present, turn the instrument off and let it cool down to room temperature (approximately 30 minutes). Turn the instrument on and place voltmeter across R26 on Detector Board. Adjust R4 for 0.475 ( $\pm 0.010$ ) VDC. Recheck voltage at TP1. Note this voltage as the new Detector Cooler voltage.

B. Detector Bias (DetBias):

1. Top of R45 or TP13 depending on board version: 120.0 ( $\pm 0.5$ ) VDC unless a tag indicates a different value: Adjust R1

C. IR Source Intensity (MTR):

1. Activate Meter (MTR) on keyboard so the Detector voltage is displayed. Adjust R16 on the Sample Control Board for a displayed detector voltage of 0.000 ( $\pm 0.100$ ) VDC.

3.3.1.3 Analog-to-Digital Converter Reference (CPU):

A. The ground is TP0, or lower left corner pad.

B. Versions with TP2 and R37 present: TP2 or U29 pin 2: 2.00 ( $\pm 0.01$ ) VDC:  
Adjust R37

C. No adjustment performed on Versions without TP2 and R37

#### 3.3.1.4 Radio Frequency Interference (RFI) Threshold: (Top of R8 is ground)

- A. Antenna must be installed.
- B. Activate MTR on keyboard.
- C. Left side of L2. If reading is 4-6 VDC, adjust R18 clockwise (CW) to read 0-1 VDC. If reading is at 0-1 VDC, adjust R18 counter clockwise (CCW) to read 4-6 VDC. When the R18 turning point is reached, turn R18 one turn clockwise. When the voltage is between 4-6 VDC the MTR should display "RADIO INTERFERENCE".

#### 3.3.2 ADJUSTMENT PROCEDURE

- A. The adjustment procedure uses certified 0.08 QAP solution and tap water. The 0.08 QAP solution should be a fresh transfer to the simulator or have been transferred on the date of adjustment as noted on the simulator label. The maximum use for any QAP solution transferred to a simulator is a single day.
- B. Record the batch number of the solution used on the QAP Worksheet and DataMaster Calibration Certificate.
- C. Use only Guth Model 34C or 2100 simulators with a thermometer that has been certified according to the Simulator Thermometer Certification procedure.
  - 1. Prior to pouring contents of solution into the simulator ensure the following routine maintenance has occurred:
    - a. Ensure the O ring is in place and shows no signs of tearing or breaking.
    - b. Dry the simulator tubing by removing excess moisture, replace tubing if necessary.
    - c. The outlet tubing from the simulator should be kept as short as possible while still allowing a connection to be made to the instrument without kinking of the tubing.
- D. The simulator inlet port should be attached to the pump via the "Calibrate" port on the instrument and the simulator outlet port to the breath tube.
- E. Set the "ETHANOL CONCENTRATION" in the supervisory options to the equivalent vapor concentration of the 0.08 QAP solution. Round the four digit equivalent vapor concentration to three digits using the common rounding method.
- F. Ensure that the simulator thermometer indicates  $34.0 \pm 0.2$  °C.
- G. Use the F1-F2 keys on the keyboard to initiate the calibration procedure.
- H. Follow the displayed instructions.

1. When the display reads "BLOW WATER VAPOR", introduce water vapor into the breath tube. Push NOVOL (NV) if necessary to accept the sample.
  2. When the display reads "BLOW ETHANOL", introduce the known ethanol solution vapor into the breath tube until a stable reading is obtained. Push NOVOL (NV) to accept the sample if necessary.
- I. Print out the calibration (CAL) factors and retain the document in the QAP file.
  - J. The Technician shall be allowed to perform the calibration procedure as often as they determine to be necessary in order to achieve optimum instrument performance. All breath test documents need to be retained.

### 3.3.3 COMPLETE CALIBRATION

The following steps shall be performed using certified QAP 0.04, 0.08, 0.10, and 0.15 solutions. The order in which the solutions are examined is left to the discretion of the Technician. Each QAP solution should be a fresh transfer to its simulator or have been transferred on the date of certification as noted on the simulator label. The maximum use for any QAP solution transferred to a simulator is a single day.

**NOTE: THE 0.08 QAP SOLUTION USED FOR THE CALIBRATION CHECK MUST HAVE A DIFFERENT BATCH NUMBER THAN THE QAP SOLUTION USED FOR THE ADJUSTMENT.**

- A. Use only Guth Model 34C or 2100 simulators which contain a certified QAP solution.
- B. Set the supervisory test option for ten tests.
- C. Set keyboard and data collection to off.
- D. Simulator check to off.
- E. Use a thermometer which has been certified according to the Simulator Thermometer Certification procedure. Verify that the thermometer indicates that the temperature of the simulator solution is  $34.0 \pm 0.2$  °C. Indicate this on the QAP Worksheet.
- F. Insert the document (except on DataMaster CDM) and push the SUP key.
- G. When the ten tests are completed indicate if temperature is  $34.0 \pm 0.2$  °C on the QAP Worksheet.
- H. Use the mean (arithmetic mean) and standard deviation values that are printed out by the DataMaster instrument to compute the % bias and the % CV. The mean and standard deviation have been rounded to four decimal places.



1. Determine the percent bias and ensure that it is within  $\pm 5.00\%$  according to the following equation:

$$\text{Bias}(\%) = \left[ \frac{\bar{Y} - R}{R} \right] \times 100$$

where:

$\bar{Y}$  = arithmetic mean

R = reference value

2. Determine the coefficient of variation according to the following equation and ensure that the result is within 3.00%:

$$\text{CV}(\%) = \left[ \frac{SD}{\bar{Y}} \right] \times 100$$

where:

SD = Standard deviation

3. The % bias and % CV shall both be rounded to two decimal places and recorded on the QAP Worksheet and the DataMaster Calibration Certificate along with the mean and standard deviation.
4. The Expanded Uncertainty value (k=2) listed on the QAP Solution Test Report must be divided by a factor of two. After dividing by two, Technicians must record the results of the calculation on the DataMaster Calibration Certificate in the appropriate column for the Combined Standard Uncertainty.
5. The results of the certification procedure will be examined to ensure they comply with the stated criteria for accuracy (% bias) and precision (% CV). If the data is found to be outside the stated criteria the Technician may, at any time during the certification procedure, terminate the QAP and repeat it in total.

### 3.3.4 PERFORM A COMPLETE BREATH TEST (VERIFICATION)

- A. Set supervisory test to one. Set Keyboard, Simulator Check, and Sample Check to "ON". Conduct a complete breath test on the instrument using a live subject's breath sample. Use a certified external standard solution.
- B. Ensure the simulator standard reads between 0.072 and 0.088, inclusive.

- C. Retain the breath test document.

### 3.3.5 PERFORM THE INTERFERENCE TEST

- A. With the keyboard set to "OFF", use a simulator containing approximately 0.08 g/210L of ethanol to which approximately 0.5 ml of acetone has been added.
- B. Verify the simulator thermometer indicates the temperature is  $34.0 \pm 0.2$  °C and conduct one supervisory test.
- C. Verify that the instrument displays INTERFERENCE DETECTED
- D. Push the ABT key and then push the COPY key and retain document in the QAP file

### 3.3.6 PERFORM THE MOUTH ALCOHOL / INVALID SAMPLE TEST

- A. Set the instrument up to perform a breath test
- B. A human subject is to exhale into the instrument during the PLEASE BLOW phase shortly after introducing into the mouth a substance containing ethyl alcohol (i.e., mouthwash, beverage alcohol, etc.)
- C. Verify that instrument displays INVALID SAMPLE
- D. Push the ABT key and then push the copy key and retain the document in the QAP file

### 3.3.7 PERFORM THE RADIO FREQUENCY INTERFERENCE (RFI) DETECTOR TEST

- A. Set the instrument up to display PLEASE BLOW
- B. Transmit a hand held (portable) police radio in the proximity of the instrument
- C. Verify that instrument displays RADIO INTERFERENCE
- D. Push the ABT key and then push the COPY key and retain the document in the QAP file

- 3.3.8 PERFORM A DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE. The diagnostic test shall be the last test performed in the QAP. Note the start time of the diagnostic test as the completion time for the end of the QAP.
- 3.3.9 The DataMaster Calibration Certificate shall be filled out when the above steps have been successfully performed as described. The Certificate will be transferred for technical and administrative review and then transferred for issuance.
- 3.3.10 The results of the certification procedure will be examined to ensure they comply with the stated tolerances of accuracy (% bias) and precision (%CV).
- 3.3.11 The Expanded Uncertainty value ( $k=2$ ) listed on the QAP Solution Test Report must be divided by a factor of two. This is automatically computed by the Calibration Certificate when documented in the appropriate column for the Combined Standard Uncertainty.
- 3.3.12 The entire QAP shall be repeated if, during the QAP the Technician is required to replace any parts or components or the readjustment of voltages that are outside of tolerances.
- 3.3.13 DataMaster (Not CDM) test document shall be preserved by photocopy. Once it's checked for accuracy and legibility the photocopy becomes the original. Carbon copies are not kept.
- 3.3.14 The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all data generated, which includes a date, have been initialed.

### **3.4 QAP REVIEW AND CERTIFICATE ISSUANCE**

Prior to installing the instrument in the field, the results of the QAP must be reviewed by both the technical/administrative reviewer and issuer of the certificate. Both reviewers must be authorized by the IDS Commander to perform these respective functions. The review conducted by the issuer and the administrative reviewer may be accomplished based on faxed or e-mailed copies of all relevant pages of documentation in the instrument record. This will include the DataMaster Calibration Certificate, the QAP Worksheet, and all instrument printouts. The DataMaster Calibration Certificate will be scanned and e-mailed to the technical/administrative reviewer. The technician shall affix signatures to the QAP Worksheet, Certificate and initial/date each additional page prior to scanning and e-mailing them to the technical/administrative reviewer. The Technician shall review scanned material for accuracy and legibility before electronically sending to the reviewer.

The reviewer of the certificate will conduct a review of the QAP, which will be documented on the QAP Review Form. The reviewer will check the technician's computations for agreement using the Excel QAP computation program. Any discrepancies identified in the review process shall be brought to the attention of the technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the review is complete and deemed acceptable, the reviewer will complete the QAP Review Form and print and sign the DataMaster Calibration Certificate. Once these documents have these identifying marks, they will become the original documents. The documents shall then be scanned and e-mailed to the issuer.

The issuer's review will be documented on the QAP Review Form. The issuer will check the Technician's computations for agreement using the Excel QAP computation program. Any discrepancies identified in the review process shall be brought to the attention of the Technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the technical/administrative and issuer review is complete and deemed acceptable, the issuer shall sign and date the QAP Review Form, print and sign the DataMaster Calibration Certificate, and notify the Technician that the instrument can be installed for use. The instrument will be considered authorized for field installation when the DataMaster Calibration Certificate has been signed by the issuer and that fact communicated to the Technician. The issuer will scan and email the DataMaster Calibration Certificate and QAP documents to IDS headquarters. The Technician may retain copies of the DataMaster Calibration Certificate, QAP Worksheet, QAP Review Form and copies of original instrument printouts for their records.

### **3.5 FIELD INSTALLATION**

Prior to re-installing the instrument in the field, complete the following:

- A. Employ the RESET OPTIONS function with the F1 and F2 keys.
- B. Turn "Daylight Savings Time" feature to off using the SET and ADV keys.
- C. Perform an External Standard Solution change.

## **4 DRAEGER ALCOTEST 9510 QUALITY ASSURANCE PROCEDURE**

The Draeger Quality Assurance Procedure (QAP) ensures the accuracy, precision and forensic acceptability of the Draeger breath test instrument for the purpose of quantitative evidential measurement of the alcohol concentration of a person's breath. The procedure evaluates critical systems within the instrument to ensure their compliance with strict predetermined criteria. When complying with the standards required in the QAP, the Draeger can be confidently placed in the field for evidential use.

When the QAP is undertaken at sites other than a permanent laboratory facility, the location should provide moderate environmental conditions of temperature and humidity as commonly found under normal laboratory conditions. Calibration shall be stopped if the Technician determines that environmental conditions in any calibration location jeopardize the results of the calibration. The transportation, handling and storage of instruments being calibrated shall be done in such a way as to protect the integrity of the instrument. While undergoing transport and whenever stored in a permanent laboratory facility, the instruments will be treated with the care deserving of a precision measurement device and any storage both before and after conducting the QAP will be in a secure, limited-access location.

For any equipment requiring transportation to sites other than the permanent laboratory facility, the transportation and handling shall be done in such a way as to protect the integrity of the equipment.

When documenting the calibration item and/or equipment used, the serial number shall act as the unique identifier, unless otherwise noted.

Throughout this procedure, all tests conducted utilizing QAP solutions must be conducted utilizing Guth model 2100 or 34C simulators containing thermometers that have been certified according to Simulator Thermometer Certification procedure.

Prior to pouring contents of solution into the simulator ensure the following routine maintenance has occurred:

- Ensure the O ring is in place and shows no signs of tearing or breaking.
- Dry the simulator tubing by removing excess moisture, replace tubing if necessary.
- The outlet tubing from the simulator should be kept as short as possible while still allowing a connection to be made to the instrument without kinking of the tubing.

### **4.1 CONDITIONS REQUIRING THE QAP**

The procedure described below is to be followed when performing the QAP on Draeger instruments. This procedure shall be completed in the following circumstances:

- A. Prior to an instrument being initially installed in the field for evidentiary use.
- B. After an instrument has been returned from service by the manufacturer.

- C. After replacing any of the following components and prior to being placed back into the field for evidentiary use:
  - 1. Measurement System Firmware (M16 Processor)
  - 2. IR-Transmitter
  - 3. IR-Detector
  - 4. Cuvette
  - 5. Fuel Cell
- D. After disassembly and then reassembly of cuvette or fuel cell.
- E. If instrument requires recalibration for any reason.
- F. At least once every 12 months.

4.1.1 If an instrument has had a current QAP performed and is in spare status, it does not need another QAP if deployed in evidential mode.

## 4.2 DRAEGER INSTRUMENT ASSESSMENT

Prior to calibrating the instrument, the “As Found” performance of the Draeger shall be assessed. The assessment may be conducted at the installation site or the laboratory. The “As Found” assessment will be completed by the Technician by running one complete breath test on the instrument. For data entry purposes the Technician performing the assessment may use their own name as the operator and terminology similar to “AS FOUND” in the subject name. The other data entry is irrelevant and need not follow any particular format. One copy of the printed breath test document shall be maintained in the calibration file along with the QAP. The results from the external standard sample on the “As Found” assessment shall be recorded by hand on the Calibration/Adjustment Record generated by the Draeger at the end of the procedure, as well as the Calibration Certificate.

- A. Acceptability of the assessment is defined as an “As Found” external standard result between 0.072 and 0.088, inclusive, for both the IR and EC. In the event that the assessment indicates an unacceptable result, the QAP is immediately halted and a supervisor is contacted.
- B. The intention of the “As Found” is to show the condition or working order of the instrument before being calibrated. Therefore, if a successful “As Found” test is obtained those results are to be recorded on the required documents. If a “Repair” is needed and no “As Found” results can be obtained the “As Found” test will not be applicable. Similarly, if the instrument was not previously calibrated within the timelines set forth in this chapter, the test will not be applicable.
- C. The “As Found” will be completed one time and those results recorded on the final Draeger Alcotest 9510 Calibration/Adjustment Record and the Draeger

Alcotest 9510 Calibration Certificate. The date of the “As Found” may or may not be the same date as the final calibration QAP procedure documents.

To complete the “As Found” the following procedure should be followed:

- A. Press the green run button on the instrument.
- B. Enter applicable data.
- C. Run a complete breath test.
- D. Sign or initial one copy of the printed document that is produced by the instrument. Maintain the document in the QAP File and enter the external standard results on the Calibration/Adjustment Record and Calibration Certificate.

### 4.3 PROCEDURE

The following shall be conducted by the Breath Test Technician performing the calibration. This procedure shall be performed when the instrument is fully warm. While conducting the following procedure the Technician shall follow the procedures outline in this chapter and the final “Draeger Alcotest 9510 Calibration Record” will be printed at the completion of the QAP. If at any point throughout the QAP, it becomes necessary to begin the entire QAP again, all of the paperwork up to that point shall be retained while noting the reason on the Draeger Alcotest 9510 Calibration/Adjustment Record that is generated by the instrument.

The Technician shall verify the active software versions match the approved software versions by the Washington State Toxicologist. The Technician shall print the active software versions. The active software printout includes all four software versions. Make sure the internal printer is on. After the software version is printed turn the internal printer off. No other documents are to be printed on the internal printer.

#### 4.3.1 Barometric Pressure Adjustment

Prior to calibration of the Draeger the current barometric pressure shall be compared to the internal pressure sensor reading of the instrument. Use a reference barometer that has been certified according to the Barometer Certification Procedure. Follow the steps below to complete this process:

- A. Select “Menu”
- B. Select “Maintenance”
- C. Select “Calibration”
- D. Select “Ambient Pressure Correction”
  - 1. Ensure the pressure listed in the box titled “Ambient Pressure” is within  $\pm 10$  Hectopascals (hPa) inclusive, of the pressure reading on the reference barometer. If the pressure reading is outside of this

setting, record the differences in the measurement on a Repair Record and change the value as indicated below. If the pressure reading is within  $\pm 10$  Hectopascals inclusive, of the reference barometer exit the screen.

2. If the value listed in the "Ambient Pressure" box lies outside the acceptable range when compared to the reference barometer, select the "EXT Pressure Meter" dialogue box and change the pressure reading to the reading found on the reference barometer.
3. Select "Save" and return to main menu.
4. When no adjustment is made to the barometric pressure the reading does not need to be recorded, only verified.

#### 4.3.2 Adjustment Procedure

When entering data at prompts on the display screen, enter the data requested. Only complete entries are accepted.

- A. Select "Menu" on the display screen
- B. Select Maintenance
- C. Select "QAP"
- D. Use a certified QAP Solution (0.08 value) (with a different batch number than the calibration) for the adjustment function. The 0.08 QAP solutions should be a fresh transfer to the simulator or have been transferred on the date of calibration as noted on the simulator label. The maximum use for any QAP solution transferred to a simulator is a single day.
- E. Select "Adjustment"
- F. Follow data entry prompts from the instrument. Only complete entries will be accepted.
- G. Connect the simulator to the instrument and follow instructions as prompted on the instrument display to successfully complete an adjustment

#### 4.3.3 Internal Standard Adjustment

After successful adjustment of the instrument the Internal Standard Adjustment Function must be completed. Follow the below steps to complete the process:

- A. Exit the QAP screen. From the Menu tab, select Maintenance
- B. Select "Calibration"
- C. Select "Internal Standard Adjust"



- D. Instrument will display “Do you really want to start an internal standard adjust?”  
Select “Yes”
- E. Once completed, return to the QAP screen and proceed to next step.

On final Draeger Alcotest 9510 Calibration Certificate a data entry section for the internal standard adjustment must be selected. Using the drop down selection menu, select, “Completed”.

#### 4.3.4 Complete Calibration

**NOTE: THE 0.08 QAP SOLUTION USED FOR THE CALIBRATION CHECKS MUST HAVE A DIFFERENT BATCH NUMBER THAN THE QAP SOLUTION USED FOR THE ADJUSTMENT.**

The following steps shall be performed using certified QAP 0.04, 0.08, 0.15, and 0.20 solutions. The order in which the calibration checks are performed is left to the discretion of the Technician. Each QAP solution should be a fresh transfer to its simulator or have been transferred on the date of certification as noted on the simulator label. The maximum use for any QAP solution transferred to a simulator is a single day.

Use only Guth Model 34C or 2100 simulators which contain a certified QAP solution. Verify that the certified thermometer indicates that the temperature of the simulator solution is  $34.0 \pm 0.2$  °C.

For each calibration concentration use the following procedure:

- A. On the QAP display select the linearity check to be performed. The display will allow you to select one of four options titled: “Lin Test 1, Lin Test 2, Lin Test 3, or Lin Test 4”. There is no particular order in which the test must be performed. However, note that Lin Test 1 will print in column one, Lin Test 2 in column two, etc.
- B. Ensure that the appropriate boxes are checked on the display screen for the QAP at the end of each linearity test.

The Technician shall be allowed to repeat the calibration steps if necessary in order to achieve optimum instrument performance. All generated documents must be retained.

#### 4.3.5 Perform the Mouth Alcohol/Invalid Sample Test

- A. Select the “INVALID SAMPLE TEST” from the menu on the instrument and follow the procedures provided by the instrument.
- B. A human subject is to exhale into the instrument during the PLEASE BLOW phase shortly after introducing into the mouth a substance containing ethyl alcohol (i.e., mouthwash, beverage alcohol, etc.).

- C. Verify that the instrument displays “INVALID SAMPLE”.
- D. Ensure the “INVALID SAMPLE” box is checked on the display screen for the QAP upon completion of the test.

#### 4.3.6 Perform the Interference Test

- A. Use a simulator containing approximately 0.08 g/210L of ethanol to which approximately 1.5 ml of acetone has been added.
- B. After selecting the “INTERFERENCE TEST” from the menu, follow the data entry procedures provided by the instrument.
- C. Verify that the instrument displays “INTERFERENCE DETECTED”.
- D. Ensure the appropriate Interference Test box is checked on the display screen for the QAP upon completion of the test.

#### 4.3.7 Perform a Complete Breath Test (Verification)

- A. Ensure that a certified, non-expired, dry gas external standard is connected to the instrument, at gas inlet #1, to complete the breath test.
- B. Select the “BREATH TEST” option on the display screen and complete the data entry as prompted.
- C. Follow instructions on the display until the breath test sequence is complete.
- D. Ensure that the external standard result reading was within 0.072-0.088 g/210L inclusive, for IR and EC.
- E. Ensure the appropriate “Breath Test” box is checked on display screen for the QAP upon completion of the test.

#### 4.3.8 QAP Printout

- A. Select the “Printout” option from the display screen.
- B. Ensure the printed document “DRAEGER ALCOTEST 9510 CALIBRATION/ADJUSTMENT RECORD” displays appropriate data entry and all tests are printed in appropriate location.
- C. The results of the certification procedure shall be examined to ensure they comply with the stated tolerances of accuracy (% bias or allowable tolerance differences as identified below) and precision (% CV).

- D. Use a calculator, the mean from each linearity test (arithmetic mean) and standard deviation values from each linearity test that are printed out by the Draeger instrument to confirm the % bias and the % CV values computed by the Draeger are correct. The mean and the standard deviation have been rounded to four decimal places.
- E. Examine the results reported on the Draeger Alcotest 9510 Calibration/Adjustment Record for each concentration and ensure that the bias is less than or equal to  $\pm 5\%$  using the formula below. If greater than 5%, the results are still satisfactory if the difference between the reference value and the sample mean is less than or equal to  $\pm 0.005$  g/210 L using the second formula below.

$$\text{Bias}(\%) = \left[ \frac{\bar{Y} - R}{R} \right] \times 100 \quad (\text{Rounded to two decimal places})$$

or  $\bar{Y} - R = \pm 0.005 \text{ g/210L of R}$

where:

$\bar{Y}$  = arithmetic mean

R = reference value

- F. Examine the results reported on the Draeger Alcotest 9510 Calibration/Adjustment Record for each concentration and ensure that the results for the coefficient of variation are within 3% according to the following equation:

$$\text{CV}(\%) = \left[ \frac{SD}{\bar{Y}} \right] \times 100 \quad (\text{Rounded to two decimal places})$$

where:

SD = Standard deviation

- G. Once the results have been confirmed to ensure they comply with the stated criteria for accuracy (% bias) and precision (% CV), if the data is found to be outside the stated criteria the Technician may terminate the QAP and repeat it in total at any time during the certification procedure.
- H. The Technician shall include all produced documents, including the 'As Found' printout to the reviewer for their review.

#### 4.3.9 Calibration Certificate

- A. The Draeger 9510 Calibration Certificate shall be filled out when the above steps have been successfully performed as described. The certificate shall be transferred for technical/administrative review and issuance as outlined in the Certificate Issuance and Technical/Administrative review section.

- B. The results of the certification procedure shall be examined to ensure they comply with the stated tolerances of accuracy (% bias) and precision (% CV).
- C. The entire QAP shall be repeated if, during the QAP the Technician is required to replace any parts or components.
- D. The Expanded Uncertainty value ( $k=2$ ) listed on the QAP Solution Test Report must be divided by a factor of two. After dividing by two, Technicians must record the results of the calculation on the Draeger Calibration Certificate in the appropriate column for the Combined Standard Uncertainty.

4.3.10 The technical record submitted by the Breath Test Technician for certificate technical/administrative review and issuance is complete when the worksheet and all data generated, which includes a date, have been initialed.

#### **4.4 CERTIFICATE TECHNICAL/ADMINISTRATIVE REVIEW AND ISSUANCE**

Prior to installing the instrument in the field, the results of the QAP must be reviewed by both the technical/administrative reviewer and the issuer of the certificate. Both reviewers must be authorized by the IDS Commander to conduct reviews/issue certificates. The review conducted by the issuer and the technical/administrative reviewer may be accomplished based on faxed or e-mailed copies of all relevant pages of documentation in the instrument record. This shall include the Draeger Calibration Certificate, the QAP Worksheet, and all instrument printouts. The signed Draeger Calibration Certificate will be scanned and e-mailed to the technical/administrative reviewer. The technician shall affix signatures to the QAP Worksheet, Certificate and initial/date each additional page prior to scanning and e-mailing them to the technical/administrative reviewer. The Technician shall review scanned material for accuracy and legibility before electronically sending to the reviewer.

The technical/administrative reviewer of the certificate shall review the QAP and the review will be documented on the QAP Review Form. The technical/administrative reviewer shall check the data entry and ensure that all data entry from the Draeger Alcotest 9510 Calibration Record matches the corresponding data on the Draeger Alcotest 9510 Calibration Certificate. The technical/administrative reviewer will ensure that the current approved software versions are installed on the instrument. The technical/administrative reviewer shall verify that all documentation is included and matches the Calibration/Adjustment record and the Calibration Certificate. The reviewer should also verify that the ethanol reference values were entered correctly. Any discrepancies identified in the review process shall be brought to the attention of the Technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the review is complete and deemed acceptable, the technical/administrative reviewer will sign and date the QAP Review Form, and print and sign the Draeger 9510 Calibration Certificate. The signed documents will then be scanned and e-mailed to the issuer.

The issuer will review the QAP and the review will be documented on the Quality Assurance Procedure Review Form Draeger Alcotest 9510. The issuer shall check the data entry and ensure that all data entry from the Draeger Alcotest 9510 Calibration Record matches the corresponding data on the Draeger Alcotest 9510 Calibration Certificate. The issuer will ensure

that the current approved software versions are installed on the instrument. The issuer reviewing the Calibration Certificate shall verify that all documentation is included and matches the Calibration/Adjustment record and the Calibration Certificate. The issuer shall also verify that the ethanol reference values were entered correctly. Any discrepancies identified in the review process shall be brought to the attention of the Technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the review is complete and deemed acceptable, the issuer shall sign and date the QAP Review Form, print and sign the Draeger 9510 Calibration Certificate. The issuer will then notify the Technician who performed the QAP that the review is complete and that the instrument can be returned to the field for evidential use.

The issuer will scan and email the Draeger Alcotest 9510 Calibration Certificate and QAP documents to IDS headquarters. The Technician may retain copies of the Draeger Alcotest 9510 Calibration Certificate, Draeger Alcotest 9510 Calibration/Adjustment Record, QAP Review Form and original instrument printouts for their records.

#### **4.5 FIELD INSTALLATION**

Prior to installing the instrument in the field, complete the following:

- Confirm both dry gas canisters have non-expired expiration dates
- Reattach the gas enclosure
- Conduct one breath test to confirm normal operation. Retain the breath test document at the local level
- Ensure the instrument has the most current drinking location codes from the Liquor Cannabis Board. This should be done on a quarterly basis.
- Ensure the supervisory key has been removed

## **5 EXTERNAL STANDARD SOLUTION CHANGING PROCEDURE**

### **5.1 POLICY**

The following protocol shall apply to qualified personnel who change external standard solutions.

### **5.2 RESPONSIBILITIES**

- Only certified personnel shall change external standard solutions.
- Certified personnel shall be responsible for monitoring and changing external standard solutions.
- Solution measurements can be monitored through the host computer or by completing a supervisor test.
- Ensure that only Guth Model 34C or 2100 simulators are employed for field use.
- External standard solutions shall be stored in secure locations with limited access. Acceptable locations include: the TLD, satellite calibration facilities and locked containers maintained by solution changers.
- External standard solutions shall be stored in climate-controlled locations under moderate conditions. External standard solutions may not be stored in vehicles other than during transport.

### **5.3 EXTERNAL STANDARD SOLUTION SUPPLY**

- Only certified external standard solutions are to be used.
- Only solutions within a sealed container labeled with the batch number and preparation date are to be used.
- Only non-expired external standard solutions are to be used.

### **5.4 EXTERNAL STANDARD SOLUTION CHANGING SCHEDULE**

- Solutions shall be changed at least every 60 days regardless of number of tests or measurement value.
- When an instrument is installed a solution change shall be performed.

### **5.5 PROCEDURE**

- A. Turn off and disconnect simulator.

- B. Discard old solution.
- C. Dry the simulator tubing by removing excess moisture, replace tubing if necessary.
- D. Check the instrument simulator ports for obvious excess moisture and dry if necessary.
- E. The outlet tubing from the simulator should be kept as short as possible.
- F. Ensure simulator elements and jar are clean and dry, pour contents of container into jar, tighten jar to simulator, and ensure the appropriate batch # label is attached.
- G. Re-attach simulator and turn on.
- H. Ensure that the thermometer indicates the correct temperature of:  $34.0 \pm 0.2$  °C and that the power and heater lamps are working properly. If the thermometer is not registering within specifications or if the power and heater lamps are not functioning properly, contact a Breath Test Technician immediately.
- I. Run one complete breath test entering data according to the steps outlined in Data Entry for Breath Test Program Personnel chapter and using a live subject's breath sample.
- J. The External Standard Solution shall read between 0.072 and 0.088, inclusive.
- K. Keep the document of the completed test. Complete the form entitled Solution Change Record recording the results to three digits.

## **5.6 ADDITIONAL RESPONSIBILITIES**

- A. Ensure that the instrument has adequate supplies: mouthpieces, breath test document, code book and printer supplies.
- B. Ensure breath tube is warm or hot to the touch.
- C. Check date and time and adjust if necessary.
- D. Check RFI antenna and phone connections.
- E. Replace "Drinking Location Codes" in code book with updates from the Liquor Cannabis Board. This should be done on a quarterly basis.

## **6 EXTERNAL STANDARD CHANGING PROCEDURE FOR DRAEGER ALCOTEST 9510 INSTRUMENTS**

### **6.1 POLICY**

The following protocol shall apply to qualified personnel who change external standard dry gas cylinders in the Draeger.

### **6.2 RESPONSIBILITIES**

- Only certified personnel shall change external standard dry gas cylinders.
- Certified personnel shall be responsible for monitoring and changing external standard dry gas cylinders.
- Ensure that only certified, non-expired, gas cylinders are used that contain an ethanol value of 0.08 g/210L. Note: The 0.08 value is the nominal value that is ordered from the supplier. During the External Standard Testing of the instrument, the result must lie between 0.072-0.088, inclusive.
- External standard dry gas cylinders shall be stored in secure locations with limited access. Acceptable locations include: Satellite calibration facilities and locked containers maintained by approved personnel approved to perform cylinder changes.
- External standard dry gas cylinders shall be stored in climate-controlled locations under moderate conditions. External standard cylinders may not be stored in a vehicle other than during transport.

### **6.3 EXTERNAL STANDARD GAS CYLINDER SUPPLY**

- Only certified external standard cylinders are to be used.
- Only cylinders labeled with a batch or lot number and expiration date are to be used.
- Only non-expired cylinders are to be used.

### **6.4 EXTERNAL STANDARD GAS CYLINDER CHANGING SCHEDULE**

The Draeger utilizes a dual tank connection. Therefore, two separate cylinders may be deployed. When the current cylinder is emptied, or reaches its expiration, it will automatically switch to the second cylinder, provided cylinder two has a non-expired tank with sufficient amount of dry gas. The cylinder expiration and volume are monitored by the instrument. The instrument does not permit an expired cylinder, or one with insufficient volume, to be used during any evidential test sequence.



Cylinders should be changed as soon as practical once insufficient volume is identified by the instrument or once a cylinder has expired. Both the expiration and/or cylinder volume may be monitored remotely if the instrument is properly connected to the data line. Additionally, a Technician may view the data on the display screen using the procedures identified below.

## 6.5 PROCEDURE

- A. Use the key to access the cylinder storage unit on the back of the instrument.
- B. Remove (if applicable) the cylinder that needs to be changed by unscrewing the cylinder from the regulator unit.
- C. Insert the new cylinder into the empty space and secure the cylinder to the regulator unit.
- D. Insert the Technician access rights USB into the Draeger to access the maintenance menu on the display screen.
- E. Select "Menu".
- F. Select "Maintenance".
- G. Select "External Standard Change".
- H. The instrument will display "Scan Operator Card" and you may select "Yes" or "No". If you choose "Yes" your operator data will automatically be entered into the instrument. If you select "No" you will need to manually enter the following data:
  1. Enter last name
  2. Enter first name
  3. Enter your operator expiration date
  4. Select the "Summary" tab on the display screen and if all of the data is correct, select the "Save" tab on the display screen.
- I. The screen will display "Install new cylinder?"; select "Yes" then enter the appropriate data as described below:
  1. Which cylinder? Choose "cylinder one or cylinder two". (Cylinder one will always be the cylinder located on the top of the storage compartment and cylinder two will always be on the bottom.) Once selected you will be prompted to confirm the cylinder you selected with "Yes" or "No".

2. Cylinder Lot Number? Enter the correct number and select “Next”. You will be prompted to enter the lot number a second time to confirm the number was entered correctly.
3. Concentration? Enter the ethanol concentration indicated on the Certificate of Analysis. Record the concentration to three decimal places. You will be prompted to enter the concentration a second time to confirm it was entered correctly.
4. Cylinder Expiration? Enter the expiration date listed on the cylinder. You will be prompted to enter the expiration date a second time to confirm the date was entered correctly.
5. Review the data as displayed on the screen to ensure it was entered appropriately and select “Save”.
6. Install cylinder into position one or two: This may be done at this time if not already completed at the beginning of the process. When this installation prompt appears and the cylinder is installed, select “OK”.

The instrument will run a series of three samples on the cylinder. Once the samples are completed a document shall be printed indicating the results of the external standard results. All three samples will be inspected to ensure that the results are each between 0.072 and 0.088 g/210L, inclusive.

Maintain the document generated by the instrument at the local level. Complete the form titled, “Cylinder Change Record” and records each of the results to three digits.

## **6.6 ADDITIONAL RESPONSIBILITIES**

- Ensure that the instrument has adequate supplies: mouthpieces, DUI arrest forms, code book, and printer supplies.
- Ensure the instrument display has the correct date and time and adjust if necessary.
- Check the data line connection to instrument.
- Update, if necessary, the “Drinking Location Codes” via USB if instrument was unable to load the information from the connected data line.

## **7 TRACEABILITY**

### **7.1 POLICY**

Traceability is established for measurement results, not for laboratories, methods or personnel. Traceability shall be established for the individual measurement results and the mean calculations resulting from all results generated within the BTP. Traceability should establish an unbroken chain of comparisons for these measurement results back to national or international measurement standards such as NIST. Traceability will allow for comparability between different analytical instruments and methods.

### **7.2 PROCEDURE**

- A. All measurement results, mean calculations, batch numbers, and reference values will be recorded on the appropriate forms.
- B. Traceability documentation of the Dry Gas Standard will be provided by the manufacturer in the form of a Certificate of Analysis (COA) and maintained by the responsible breath test Technician.
- C. A copy of the Simulator Solution Test Report issued by the TLD shall be maintained by the responsible Breath Test Technician. This Report will record the simulator solution batch number along with all measurement results obtained by the analysts in the TLD. The Report will also contain the results of control measurements along with the control lot number and reference value. One control measurement shall be performed along with the set of five aliquots of the simulator solution. All control measurements performed shall be within  $\pm 10\%$  of the control reference value which will ensure the accuracy of the gas chromatograph instrument and the resulting reference value assigned to the simulator solutions.
- D. The TLD shall obtain and maintain a Certificate of Analysis (COA) from the reference material producer of the controls they purchase to be used during the testing of simulator solutions. The COA shall specify the lot number and reference value assigned to the purchased control solutions. The COA should also specify that the measurements performed by the manufacturer of the controls have been performed by methods and equipment that also measured Standard Reference Materials obtained from NIST.
- E. The following documents shall document and ensure traceability:
  - 1. The COA from the commercial manufacturer of the standards and controls
  - 2. The Simulator Solution Test Report
  - 3. The Calibration Certificate
- F. The traceability links will be from:

1. The measurement results and mean reported on the Calibration Certificate to:
2. The measurement results and mean reported on the Simulator Solution Test Report to:
3. The control measurement results along with lot number and reference value for the controls reported on the Simulator Solution Test Report to:
4. NIST as documented on the COA from the control manufacturer, where applicable.

## 8 ALCO-SENSOR PBT CERTIFICATION PROTOCOL

### 8.1 POLICY

Certified PBT Technicians within the BTP shall be responsible for certifying the PBT instruments used only by members of the WSP. Certifying PBT instruments owned and operated by other agencies shall not be the responsibility of members of the BTP. However, this does not preclude the certifying of PBT instruments owned and operated by other agencies. This shall only be done in a limited number of circumstances and only when it is in the best judgment of the PBT Technician.

### 8.2 PROCEDURE FOR ALCO-SENSOR FST PBT

- A. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.
- B. Use the altitude chart or altitude correction factor on the side of the tank to determine the adjusted reference value.
- C. Attach a new mouthpiece and power the instrument on by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.
- D. The display should show the **RCL** message, which is the first option in the function menu. Momentarily depress and release the **ON** button until the displayed message reads ACC.
- E. With **ACC** on the display, press the **OFF** button to select the Accuracy Check option. The temperature will be displayed. Ensure a Blank Test result of 0.000 g/210L is displayed. A flashing **ACC** message will appear.
- F. While the display is flashing **ACC**, make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.
- G. Depress the regulator control button for approximately seven (7) seconds. At approximately five (5) seconds depress and release the **ON** button (while the gas continues to flow) to manually accept the sample. Some of the newer or modified regulators will dispense the gas at a higher rate enabling the FST to automatically accept the sample and eliminating the need to manually accept the sample.
- H. The result will automatically be displayed.
- I. If the results are within  $\pm 0.010$  g/210L from the adjusted reference value for the gas standard, the PBT is properly calibrated and acceptably accurate and only one test is necessary. Proceed to the Record Keeping steps.
- J. If the result is not within the acceptable limits, proceed to the Calibration process.

### 8.3 CALIBRATING THE ALCO-SENSOR FST PBT INSTRUMENT

- A. To calibrate the instrument its temperature must be between 20 °C and 35 °C. If the temperature is not within the range, the unit will display **E09** or **E10** and block the calibration procedure.
- B. Attach a new mouthpiece and power the instrument **ON** by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.
- C. The display should show the **RCL** message, which is the first option in the function menu. Momentarily depress and release the **ON** button until the displayed message reads **CAL**.
- D. Once **CAL** is displayed, depress the **OFF** button, this will initiate calibration sequence.
- E. The temperature will be displayed, ensure a Blank Test result of 0.000 g/210L is also displayed. A flashing **CAL** message will appear.
- F. While the display is flashing **CAL**, make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.
- G. Depress the regulator control button for approximately seven (7) seconds. At approximately five (5) seconds depress and release the **ON** button (while the gas continues to flow) to manually accept the sample.
- H. The result will automatically be displayed. If the result equals the expected value of the standard depress the **OFF** button. You will see that each time you depress the **OFF** button, the cursor moves from the left most digit of the number to the right. After depressing the button three times, the value displayed will be accepted as the calibration value and will flash three times before the instrument will power down.
- I. If the result **does not** match the expected value of the standard gas, you will need to adjust the displayed result to the proper value. The result displayed will have the digit furthest to the left flashing. If the flashing digit is incorrect, press and release the **ON** button as many times as it is necessary to cycle the displayed digit to the correct number. When the digit is correct, press the **OFF** button to move the flashing highlight to the digit to the right. After you have adjusted the furthest to the right digit and the **OFF** button is depressed, the new calibration value will be flashed on the display three times. If you need to adjust this number further, pressing the **OFF** button again, while the entire calibration number is flashing, will provide you this option by displaying the most recently entered number with the digit furthest to the left flashing. If the calibration value is correct and you have not pressed the **OFF** button a second time, after the third flash the new calibration value will be accepted.
- J. Cycle the power on the instrument **OFF** and **ON** and repeat the certification process to verify the accuracy of the instrument.

#### 8.4 PROCEDURE FOR ALCO-SENSOR III PBT

- A. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.
- B. Use the altitude chart or altitude correction factor on the side of the tank to determine the adjusted reference value.
- C. Verify the PBT temperature is between 20.0 °C and 36.0 °C.
- D. Push **SET** button. Push and hold the **READ** button.
- E. The digits should go to 0.003 or less within 10 seconds. If the digits do not go to 0.003 or less, push **SET**, wait one minute and push and hold the **READ** button again.
- F. Attach the straight white tube mouthpiece to the instrument receptacle.
- G. Attach mouthpiece to the gas standard source and provide the sample. Allow approximately three seconds of gas flow.
- H. Push and hold the **READ** button while the sample is still being provided. Continue to hold the **READ** button until the result stabilizes.
- I. If the results are within  $\pm 0.010$  g/210L from the adjusted reference value for the gas standard, the PBT is properly calibrated and acceptably accurate and only one test is necessary. Proceed to Record Keeping steps. If the result is not within the acceptable limits, proceed to the Calibration process.

#### 8.5 CALIBRATING THE ALCO-SENSOR III PBT INSTRUMENT

- A. If the result is outside  $\pm 0.010$  g/210L of the adjusted reference value, first zero the instrument to 0.003 or less, then turn the calibration screw clockwise two full turns.
- B. Re-introduce the gas standard and while holding the **READ** button, turn the calibration screw counter-clockwise slowly to value on gas standard. Avoid adjusting to below the reference gas standard value during this procedure.
- C. Repeat steps Calibration steps as often as necessary to obtain results within the acceptable range.
- D. If results following calibration are acceptable, only perform one certified test.
- E. Where instruments are not outside  $\pm 0.010$  g/210L, Technicians are authorized to make small calibration adjustments without first turning the calibration screw clockwise two full turns. Following all calibration adjustments, a complete test shall be performed.

## **8.6 DOCUMENTATION**

- A. Complete the PBT Certification Record.
- B. Record results to three decimal places.
- C. Note if it was necessary to calibrate the instrument.
- D. Documentation shall be retained at the satellite laboratories.

## **8.7 FREQUENCY OF PBT CERTIFICATION**

The PBT instruments are to be certified at least every six months according to the Washington Administrative Code (WAC) 448-15-040.



## 9 DATA ENTRY FOR BREATH TEST PROGRAM PERSONNEL

### 9.1 POLICY FOR DATAMASTER INSTRUMENTS

For uniformity, the following data entry codes are to be used by Breath Test Technicians and Solution Changers when performing breath tests on DataMaster instruments for new solutions, tests, etc. that will appear in the database.

#### 9.1.1 Data Entry Format

Simulator temp.?	Y
Observation Began	00:00
Citation Number	New/Solution
Operator	Correct Name
Arresting Agency	WSP1057
Subject's Name	NEW/SOLUTION,
Subject's DOB	00/00/0000
Subject's Sex	M
Subject's Ethnic Group	U
D.L. State/Number	OO
County of Arrest	00
Crime Arrested For	00
Collision Involved?	N
Drinking Location	00000000
Batch #	Correct Number
PBT TEST GIVEN? (Y/N)	N

### 9.2 POLICY FOR DRAEGER 9510 INSTRUMENTS

For uniformity, the following data entry codes are to be used by Breath Test Technicians and External Standard changers when performing breath tests on Draeger instruments for tests that will appear in the database.

#### 9.2.1 Data Entry Format For Draeger 9510

Observation time	00:00
Operator observed subject entire time?	Y
Subject smoke, vomit, put anything in mouth?	N
Citation/case number	000000
County of arrest	00-39
Crime arrested for	00
Collision involved	N
Subject drinking as specific establishment	N (FOLLOW PROMPTS)
PBT given	N
Operator name	TYPE IN OR SCAN CARD
	Last
	First

Operator Agency Code  
Subject ethnic group  
Subject driver's license  
Subject name field

Middle  
WSP1057  
UNKNOWN  
new/cylinder  
new/cylinder

## 10 BREATH TEST INSTRUMENT CODE INTERPRETATION

### 10.1 DATAMASTER POLICY

The DataMaster breath test instrument will record and store in memory the occurrence of several different codes. These are ultimately downloaded to the host computer for storage in the instruments database. The following is a list of the codes generated by the instrument and their interpretation.

### 10.2 NUMERIC CODE AND INTERPRETATION

CODE NUMBER	MESSAGE CODE	INTERPRETATION
1.*	SYSTEM WON'T ZERO	Unable to zero detector voltage.
2.	TEMPERATURE LOW	Sample chamber temperature at 45 °C or above
3.	TEMPERATURE HIGH	Sample chamber temperature at 55 °C or above.
5.*	RADIO INTERFERENCE	Radio frequencies detected.
6.	FATAL SYSTEM ERROR (ADDRESS)	Random Access Memory (RAM), Read Only Memory (ROM), or Peripheral Interface Adapter (PIA) not responding properly.
7.*	CALIBRATION ERROR	Internal standard does not read within 10% of the value determined at time of calibration.
8.*	PRINTER ERROR	Printer not responding properly.
9.*	RAM ERROR (ADDRESS)	RAM checksum does not match the value calculated following the last write.
10.	PUMP ERROR	Flow detector does not detect pump operation.
11.	BLANK ERROR	Instrument obtains reading greater than 0.003 g/210L during blank test.
12.	DETECTOR OVERFLOW	Detector output exceeds the 1.999V that is readable by the instruments Analog/Digital converter.
13.	FILTER ERROR	Filter solenoid not activating properly.
15.	SIMULATOR OUT OF RANGE	Simulator reading outside acceptable limits.
17.	DATA MEMORY BATTERY LOW	RAM battery backup failing.
19.	AMBIENT FAIL	Ethanol or other substance detected in sample chamber after purge.
20.	SAMPLES OUTSIDE 10%	Samples were outside of acceptable parameters.

### 10.3 NON-NUMERIC CODE AND INTERPRETATION

V	INVALID SAMPLE
R	REFUSED TEST
X	INTERFERANT
I	INCOMPLETE TEST

\* Codes found in the DataMaster instruments prior to 1995

## 10.4 DATAMASTER HELPS

### 10.4.1 Policy

The DataMaster will generate several different error messages when specific criteria are not met during a test procedure. These messages are displayed on the instrument for the operator to respond to. The following are the messages that an operator may see and their interpretation. In addition, specific instructions for the operator are given here. This list should be posted on the wall near every DataMaster evidential breath test instrument in field use. The instructions provided here are considered guidelines only. They are not mandatory. Qualified operators may use their own training and discretion in responding to these messages.

MESSAGE DISPLAYED	INTERPRETATION AND INSTRUCTIONS
INVALID SAMPLE	Check Mouth, wait 15 minutes, try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
AMBIENT FAIL	Check for odors, check to see if mouth piece is removed, try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
SYSTEM WON'T ZERO	Unable to zero detector voltage. Try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
DETECTOR OVERFLOW	Try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
RADIO INTERFERENCE	Radio transmission detected, remove source, rerun test.
CALIBRATION ERROR	Try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
INTERFERENCE DETECTED	Try one more test, if interference is noted on the second test, consider obtaining a blood sample.
SAMPLES OUTSIDE 10%	Try one or more tests. Coach the subject to provide similar samples to the instrument.
SIMULATOR OUT OF RANGE	Simulator reading outside of 0.072-0.088 inclusive limits. Call <b>WSP</b> and <b>TAG</b> instrument "Out of Service". Go to another instrument to perform the test.
PRINTER ERROR	Call <b>WSP</b> ; <b>TAG</b> the instrument "Out of Service". Go to another instrument.
JAMMED/ILLEGIBLE DOCUMENT**	Printer not performing properly. Call <b>WSP</b> ; <b>TAG</b> the instrument "Out of Service". <b>Do not</b> press RUN.
BLANK ERROR	Try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out

	of Service"
<b>FILTER ERROR</b>	Try one or more tests and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
<b>TEMPERATURE LOW</b>	Out of service, call <b>WSP</b> and <b>TAG</b> instrument "Out of Service"
<b>TEMPERATURE HIGH</b>	Out of service, call <b>WSP</b> and <b>TAG</b> instrument "Out of Service"
<b>FATAL SYSTEM ERROR</b>	Out of service, call <b>WSP</b> and <b>TAG</b> instrument "Out of Service"
<b>RAM ERROR</b>	Out of service, call <b>WSP</b> and <b>TAG</b> instrument "Out of Service"
<b>PUMP ERROR</b>	Try one more test and then call <b>WSP</b> if fails. <b>TAG</b> instrument "Out of Service"
<b>DATA MEMORY BATTERY LOW</b>	Out of service, call <b>WSP</b> and <b>TAG</b> instrument "Out of Service"
<b>EXTERNAL STANDARD TEMPERATURE</b>	The simulator temperature must be within 0.2 (two lines above or below) of 34.0 °C.
<b>OUT OF SERVICE</b>	Call <b>WSP</b> at _____ and advise specific problem, serial number and <b>TAG</b> instrument out of service.

## 10.5 DRAEGER ALCOTEST 9510 POLICY

The Draeger 9510 breath test instrument will record and store in memory the occurrence of several different codes. These are ultimately downloaded to the server for storage in the instruments database. The following is a list of the codes generated by the instrument and their interpretation.

### 10.5.1 Draeger Numeric and Code Interpretation

status code id	status text string	Offer restart test with previous data option	Purge and remain in test sequence	Print test record	Disable instrument	Description	Remedy Action
1	TEST ABORTED					Test procedure was aborted	Status code is for information only. No remedy required.
3	CAL GAS SUPPLY				X	Minimum flow not observed from drygas cylinder or simulator.	Check to see if cylinder is empty or if tubing from drygas regulator is properly connected. If using simulator, check tubing connections between simulator and instrument. Contact WSP technician
4	ADJUST ERROR					Observed only in calibration procedures. An IR or EC sensor calibration factor required a significant change.	Technician can manually adjust alcohol calibration factors closer to target and repeat QAP Calibration.
5	BLANK ERROR	X				The difference between the pre- and post purge IR output is too high	Ensure ambient air is free of alcohol vapor.
6	AMBIENT FAIL	X				After purging, the calculated e-reading too high	Ensure ambient air is free of alcohol vapor.
7	INVALID SAMPLE - MUST COMPLETE NEW OBSERVATION PERIOD					Mouth alcohol is detected	Status code relates to analyzed sample. No instrument remedy required. Perform a new observation period and repeat the test.
8	INTERFERENT DETECTED	X				Interfering substances are detected	Status code relates to analyzed sample. Instrument will offer opportunity to start new test sequence retaining previously-entered data.
9	DETECTOR OVERFLOW					The calculated alcohol concentration exceeded the maximum range of the instrument.	Status code is for information only. No remedy required. Follow WSP procedures regarding possibly dangerously intoxicated subject.
10	SAMPLES OUTSIDE 10%	X				The comparison of calculated breath test results failed. IR values from subject sample 1 and 2 were compared and exceeded the required acceptable limits.	Status code relates to analyzed sample. Instrument will offer opportunity to start new test sequence retaining previously-entered data.
11	DETECTOR OVERFLOW	X				Calculated breath test concentration > max. range +25%	Status code is for information only. No remedy required. Follow WSP procedures regarding possibly dangerously intoxicated subject.
12	ALC. CONC. NOT STABLE		X			Requirements for plateau detection of the IR profile plot are not met. Continues within the 120 sec time, 3 seconds "TAKE BREATH" then "PLEASE BLOW"	Status code is for information only. Instruct subject to provide more volume in next sample attempt.
13	BLOWING NOT ALLOWED		X			Flow is detected when the instrument is not expecting a flow	Status code is for information only. Ensure blowing does not occur unless PLEASE BLOW appears on the display.
14	TIMED OUT	Operator dependent	Operator dependent	Operator dependent		Maximum time for delivering a breath sample is expired. Will be followed with window: "REFUSAL INCOMPLETE CONTINUE"	Provide breath sample soon after PLEASE BLOW first appears on the display.
15	BLOWINGTIME TOO SHORT		X			Blowing time of subject is too low. Continues within the 120 sec time, display for 3 seconds "TAKE BREATH" then "PLEASE BLOW"	The instrument will initiate another breath sample attempt.
17	MIN VOLUME NOT ACHIEVED		X			Delivered blowing volume is too low. Continues within the 120 sec time, display for 3 seconds "TAKE BREATH" then "PLEASE BLOW"	The instrument will initiate another breath sample attempt.
21	EXT. STANDARD FAILED				X	The calculated gas concentration did not meet the tolerance limits	Contact WSP technician
23	COMMUNICATION ERROR	N/A during breath test	N/A during breath test	N/A during breath test	N/A during breath test	A communication exception occurred between processors within the instrument	Turn instrument off and on. If status message persists, contact WSP technician.

status code id	status text string	Offer restart test with previous data option	Purge and remain in test sequence	Print test record	Disable Instrument	Description	Remedy Action
45	DATALOG ERROR				X	A problem was observed while sending or storing information to the database	Contact WSP technician
46	REFUSAL			X		Subject Refusal	Status code is for information only based on operator assessment that subject refused to provide breath samples. No instrument remedy required. Follow WSP procedures for handling subject refusals.
49	OPERATOR TIMEOUT					Time for operator's response (e.g. no button pressed on message box) is expired	Perform another test and complete the test sequence answering all operator prompts without leaving the instrument idle for extended periods of time.
50	PUMP ERROR 2		X			Due to alcohol in the ambient air, instrument was not able to sufficiently clear the cuvette following a high concentration sample.	Ensure ambient air is free of alcohol vapor
51	PRINTER ERROR				X	A hardware-related problem with the internal printer. Although the internal printer is not required in normal circumstances for Evidential Breath Tests, it is a fault that must be addressed.	Contact WSP technician
52	SMARTCARD PIN ERROR				X	Problem with smartcard that can cause problems with communication with the host PC.	Contact WSP technician
53	SMARTCARD TIME ERROR				X	Problem with smartcard that can cause problems with communication with the host PC.	Contact WSP technician
54	SMARTCARD CANCEL ERROR				X	Problem with smartcard that can cause problems with communication with the host PC.	Contact WSP technician
55	SMARTCARD LOCK ERROR				X	Problem with smartcard that can cause problems with communication with the host PC.	Contact WSP technician
56	INCOMPLETE TEST	X		X		Operator terminated test sequence with Incomplete test assessment.	Status code is for information only based on operator assessment that the test should be terminated as an incomplete test. No instrument remedy required. Instrument will offer operator opportunity to start a new test with the previously entered data ret
61	EC AGING COMP. ERROR				X	A problem was observed with the aging compensation algorithm, caused by an invalid time difference.	Contact WSP technician
68	DIAGNOSTIC CHECK FAILED					Any of the internal functionality tests were outside of tolerance	Repeat test. If problem continues contact WSP technician.
70	DRYGAS CHECK ERROR				X	An empty or expired drygas cylinder was observed while checking the pressure of the dry gas cylinder(s).	Contact WSP technician
71	EC_SENSOR_STRESSED					This error would only be encountered by a WSP technician. This error is only applicable during a calibration procedure (like QAP Calibration) and may occur when the EC sensor's alcohol load is too high due to previously performed tests (many tests and/or	Wait the time recommended by the instrument.



## 10.6 DRAEGER HELP SHEET

### DRAEGER ALCOTEST 9510- OPERATOR'S MANUAL

#### STATUS MESSAGES AND REMEDIES

Status Code	Description	Remedy
TEST ABORTED	TEST PROCEDURE WAS MANUALLY ABORTED.	NO REMEDY REQUIRED.
CAL GAS SUPPLY	DRY GAS EXTERNAL STANDARD ERROR.	<b>CONTACT WSP- INSTRUMENT OUT OF SERVICE</b>
BLANK ERROR	PRE- AND POST PURGE IR OUTPUT IS TOO HIGH.	ENSURE AMBIENT AIR IS FREE OF ALCOHOL VAPOR.
AMBIENT FAIL	AFTER PURGING, THE CALCULATED EC-READING IS TOO HIGH.	ENSURE AMBIENT AIR IS FREE OF ALCOHOL VAPOR.
INVALID SAMPLE- MUST COMPLETE NEW OBSERVATION PERIOD	MOUTH ALCOHOL IS DETECTED.	NO INSTRUMENT REMEDY REQUIRED. <b>PERFORM A NEW OBSERVATION PERIOD AND REPEAT THE TEST.</b>
INTERFERENT DETECTED	INTERFERING SUBSTANCES ARE DETECTED.	INSTRUMENT WILL OFFER OPPORTUNITY TO START NEW TEST SEQUENCE RETAINING PREVIOUSLY ENTERED DATA.
DETECTOR OVERFLOW	THE CALCULATED ALCOHOL CONCENTRATION EXCEEDED THE MAXIMUM RANGE OF THE INSTRUMENT.	NO REMEDY REQUIRED. FOLLOW WSP PROCEDURES REGARDING POSSIBLE DANGEROUSLY INTOXICATED SUBJECT.
SAMPLES OUTSIDE 10%	COMPARISON OF CALCULATED BREATH TEST RESULTS FAILED.	INSTRUMENT WILL OFFER OPPORTUNITY TO START NEW TEST SEQUENCE RETAINING PREVIOUSLY ENTERED DATA.
ALC. CONC. NOT STABLE	REQUIREMENTS FOR PLATEAU DETECTION OF THEIR PROFILE ARE NOT MET.	INSTRUCT SUBJECT TO PROVIDE MORE VOLUME IN NEXT SAMPLE ATTEMPT
BLOWING NOT ALLOWED	FLOW IS DETECTED WHEN THE INSTRUMENT IS NOT EXPECTING A FLOW.	ENSURE BLOWING DOES NOT OCCUR UNLESS "PLEASE BLOW" APPEARS ON THE DISPLAY.
TIMED OUT	MAXIMUM TIME FOR DELIVERING A BREATH SAMPLE IS EXPIRED. WILL BE FOLLOWED WITH THE OPTIONS "REFUSAL", "INCOMPLETE", "CONTINUE".	PROVIDE BREATH SAMPLE SOON AFTER "PLEASE BLOW" IS DISPLAYED.
BLOWING TIME TOO SHORT	BLOWING TIME OF SUBJECT IS TOO LOW.	THE INSTRUMENT WILL INITIATE ANOTHER BREATH SAMPLE ATTEMPT.
MIN. VOL. NOT ACHIEVED	DELIVERED BLOWING VOLUME IS TOO LOW.	THE INSTRUMENT WILL INITIATE ANOTHER BREATH SAMPLE ATTEMPT.
EXT. STANDARD FAILED	GAS CONCENTRATION DID NOT MEET THE TOLERANCE LIMITS	<b>CONTACT WSP- INSTRUMENT OUT OF SERVICE</b>
REFUSAL	SUBJECT REFUSAL	NO INSTRUMENT REMEDY REQUIRED.
INCOMPLETE TEST	OPERATOR TERMINATED TEST SEQUENCE WITH INCOMPLETE TEST ASSESSMENT.	NO INSTRUMENT REMEDY REQUIRED.

EC_SENSOR_STRESSED	THE EC SENSOR'S ALCOHOL LOAD IS TOO HIGH DUE TO PREVIOUSLY PERFORMED TESTS.	WAIT THE TIME RECOMMENDED BY THE INSTRUMENT.
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\*ALL OTHER STATUS MESSAGES: **CONTACT WSP-INSTRUMENT OUT OF SERVICE.**

## **11 DIGITAL REFERENCE THERMOMETER CERTIFICATION**

### **11.1 POLICY**

Digital reference thermometers are to be certified for compliance with this policy at least once every 12 months.

### **11.2 PROCEDURE**

Digital reference thermometers are to be submitted to a NIST Traceable calibration laboratory for testing. The laboratory is to be capable of providing calibration certificates traceable to NIST or a similar national or international reference standard.

### **11.3 RECORDS RETENTION**

- Records received from the calibration laboratory shall indicate that the digital reference thermometer was tested, adjusted if necessary and returned properly calibrated.
- Records received from calibration laboratory are to be maintained as part of the BTP's regular business records.
- The BTP Headquarters shall maintain the original certificates received from the calibration laboratory.
- The Breath Test Technician shall maintain copies of the certificate received from the calibration laboratory.

## **12 MULTI-METER CERTIFICATION**

### **12.1 POLICY**

Multi-meters are to be certified for compliance with this policy at least once every 12 months.

### **12.2 PROCEDURE**

Multi-meters are to be submitted to a calibration laboratory for testing. The laboratory is to be capable of providing calibration certificates traceable to NIST or a similar national or international reference standard.

### **12.3 RECORDS RETENTION**

- Records received from the calibration laboratory shall indicate that the multi-meter was tested, adjusted if necessary and returned properly calibrated.
- Records received from the calibration laboratory are to be maintained as part of the BTP's regular business records.
- The BTP Headquarters shall maintain the original certificates received from the calibration laboratory.
- The Breath Test Technician shall maintain copies of the certificate received from the calibration laboratory.

## 13 SIMULATOR THERMOMETER CERTIFICATION

### 13.1 POLICY

All Guth Model 34C or Guth Model 2100 simulators used during the performance of field evidentiary breath tests or the QAP are to employ a thermometer that has been verified for accuracy at least once every 12 months. Following certification, the thermometers are considered suitable for use for a 12 month period. When a simulator is reassigned from one instrument to another the thermometer shall be verified for accuracy. A new thermometer certification record shall be entered into instrument tracking.

### 13.2 PROCEDURE

- A. Have the mercury thermometer to be tested placed in a fully warm and equilibrated Guth Model 34C simulator.
- B. Install the standard reference thermometer probe in the same simulator in the location designed for this purpose. For the Guth Model 2100, place the probe within the same Guth Model 2100 simulator being evaluated.
- C. Ensure that the temperatures of both the tested thermometer and the standard reference thermometer have stabilized.
- D. Ensure the tested thermometer indicates a temperature within  $\pm 0.10^{\circ}\text{C}$  inclusive of the standard reference thermometer. Record the fully displayed standard reference thermometer results (including all digits) on the record form. Record also the result indicated on the mercury thermometer to the second decimal place which will have to be estimated.
- E. If the thermometer results are acceptable, record "Yes" in the thermometer certification record.
- F. If the thermometer results are not acceptable record "No" on the thermometer certification record. Depending on the type of thermometer, one of the following steps may be followed:
  1. Mercury thermometer: check for separation of mercury and attempt to correct
  2. Digital thermometer: send back to Guth
- G. After performing one of these steps, complete again the above procedure
- H. Retain the forms in the appropriate files as part of the laboratory's regular business records. Forms are to be kept by the local responsible Technician only.
- I. If the thermometer does not comply with the standards outlined above then a new thermometer shall be installed (in the case of the mercury thermometer) or

re-calibrated (in the case of the digital simulator) and a repair record shall be completed. The new thermometer shall be certified as outlined in this policy.

- J. If a thermometer is ever found to exceed the limits of  $34.0 \pm 0.2$  °C, then the thermometer must be re-calibrated and certified according to the procedure outlined in this policy.

## **14 BAROMETER CERTIFICATION**

### **14.1 POLICY**

Barometers used to check the ambient air pressure sensor contained within the Draeger instrument shall be certified for compliance with this policy at least once every 12 months.

### **14.2 PROCEDURE**

Reference barometers shall be checked for accuracy at least once every 12 months by submitting the device to an approved vendor for certification. The approved vendor must perform the accuracy testing and provide a calibration certificate traceable to NIST or a similar national or international reference standard. Reference barometers shall be sent in for annual certification by the BTP Headquarters. Once certified, the records shall be maintained at the BTP Headquarters.

### **14.3 RECORDS RETENTION**

- Records received from the calibration laboratory shall indicate that the reference barometer was tested, adjusted if necessary and returned properly calibrated.
- Records received from the calibration laboratory are to be maintained as part of the BTP's regular business records.
- The BTP Headquarters shall maintain the original certificates received from the calibration laboratory.
- The Breath Test Technician shall maintain copies of the certificate received from the calibration laboratory.

## **15 BREATH TEST INSTRUMENT REPAIR/ADJUSTMENT FORM**

### **15.1 POLICY**

The following policy shall apply when completing the Repair/Adjustment Form. This policy shall apply to those repairs made to field breath test instruments and simulators and not sub-components thereof, which have been replaced. The purpose is to provide guidelines for when it is to be completed and the information it should contain.

### **15.2 PROCEDURE**

- A. The form is to be completed only by certified Breath Test Technicians.
- B. The form shall be written clearly and concisely to allow others to interpret the information.
- C. The form needs to be completed in the following situations:
  - 1. Replacement of any components or parts not included as exceptions below
  - 2. Repair to any components or parts
  - 3. Adjustments to any potentiometer that is outside of manufacturer's specifications
  - 4. Adjustment of the instrument clock if it is more than 20 minutes off
  - 5. Replacement of the simulator
  - 6. Replacement or recalibration of the simulator thermometer: Ensure all serial numbers, magnitude and direction of deviation, and reasons for replacement are documented. Also ensure that the replacement thermometer is certified according to the Simulator Thermometer Certification chapter.
  - 7. Temperature adjustment that is outside  $34.0 \pm 0.2$  °C
  - 8. Repairing simulator stirring mechanism
- D. Instrument Re-calibration (except where part of the routine QAP)
- E. Other necessary repairs or adjustment to restore an instrument to proper working order
- F. When a repair is performed requiring the form to be completed, a complete breath test shall be conducted and noted on the form. When conducting the complete breath test the printer shall be turned off. When in the discretion of the Technician the particular repair will not influence the analytical performance of the instrument (e.g., correcting the clock time) then a complete breath test is not required.



G. The form shall not be completed in the following situations:

1. Prior to the instrument's initial QAP
2. Powering the instrument off and on to clear a lock-up condition
3. When changing time to correspond to changes in daylight saving time
4. When removing a stuck ticket when there is no apparent problem with the printer
5. When problem is due to operator error
6. Obtaining copies of ticket for operators when there is no apparent printer problem
7. When the display indicates any of the possible error messages and the problem is corrected on the subsequent test. A record of these situations is preserved in the database
8. When the problem is corrected over the phone with an operator or Solution Changer
9. When performing routine purging of the instrument
10. When replacing simulator tubing
11. When an instrument is transferred to a permanent training status
12. When replacing a normally worn or faded printer ribbon or toner cartridge
13. As part of the routine QA

## **16 ESTIMATION OF MEASUREMENT UNCERTAINTY**

### **16.1 POLICY**

Measurement uncertainty will be estimated for the values assigned to breath alcohol reference materials and for the results obtained during calibration of the breath alcohol measuring instruments. The BTP and the TLD have attempted to identify all the components of uncertainty contributing to each of these calibration categories and have made reasonable estimates of each component for inclusion in their respective uncertainty budgets. The estimation of uncertainty does not replace any existing policies established for the maintenance of quality control nor does it supersede any established legal, statutory or regulatory guidance on breath alcohol testing or breath alcohol measuring instrument calibration.

Uncertainty is not synonymous with error, inaccuracy or bias. Restrictions on measurement error have been integrated into the procedures for reference material certification and instrument calibration. Refer to DataMaster QAP and Draeger Alcotest 9510 QAP chapters of this Technical Manual for a description of the restrictions applicable to breath alcohol measuring instrument calibration.

This policy applies only to the functions of the BTP and TLD's breath alcohol calibration program as defined in its scope of accreditation. The application of measurement uncertainty to individual breath alcohol tests is not covered by this policy and any such calculations should not be construed as having either been reviewed or endorsed by representatives of any accrediting organization.

### **16.2 UNCERTAINTY BUDGET**

An uncertainty budget describes those components that have been identified as contributing to the overall measurement uncertainty for a given calibration activity. These components include contributions from reference standards, inexact values of reference materials, equipment used, approximations in the measurement procedure, inexact values of constants and variations in repeated observations (repeatability). Multiple sources may contribute to a single uncertainty component. When a component is estimated from a source external to the BTP or TLD, it is first converted to its standard uncertainty based on the reported coverage factor.

Figure 1 is a cause and effect diagram showing the uncertainty sources incorporated into the budget for the breath alcohol reference materials. It applies to both the external standard solution and the quality assurance procedure solutions. There are four major components that contribute to the overall uncertainty and they are broadly categorized as: analytical, repeatability, reference materials and external constants.

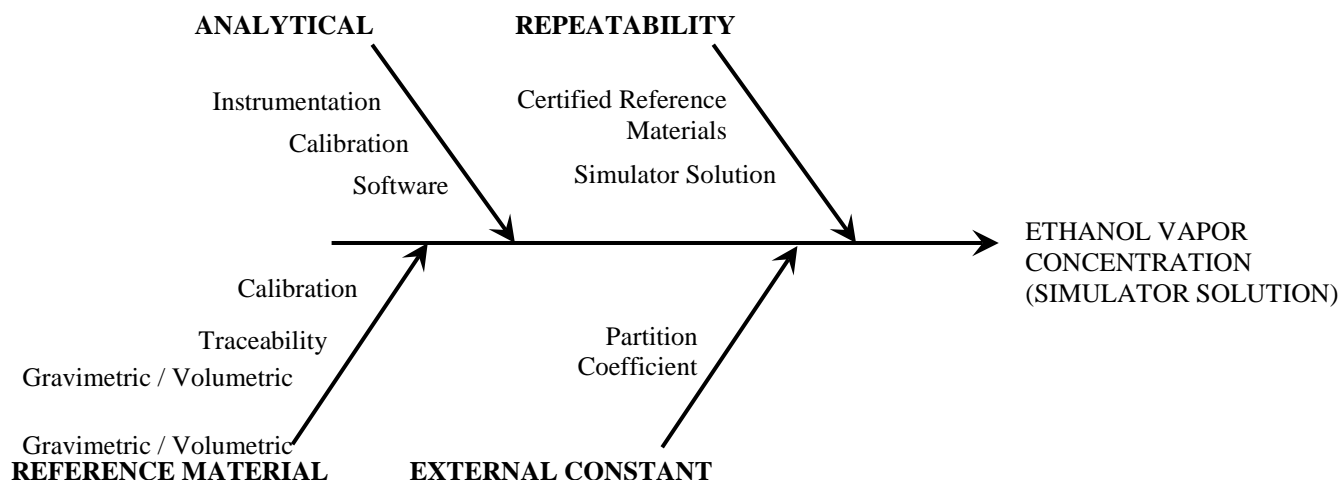


Figure 1: Cause and effect diagram for the breath alcohol calibration reference materials

Figure 2 is the cause and effect diagram for the uncertainty sources contributing to the breath alcohol measuring instrument's calibration uncertainty. It includes all the components in figure 1 and adds the variability of repeated measurements of the QAP solution measured using the Breath Test Instrument.

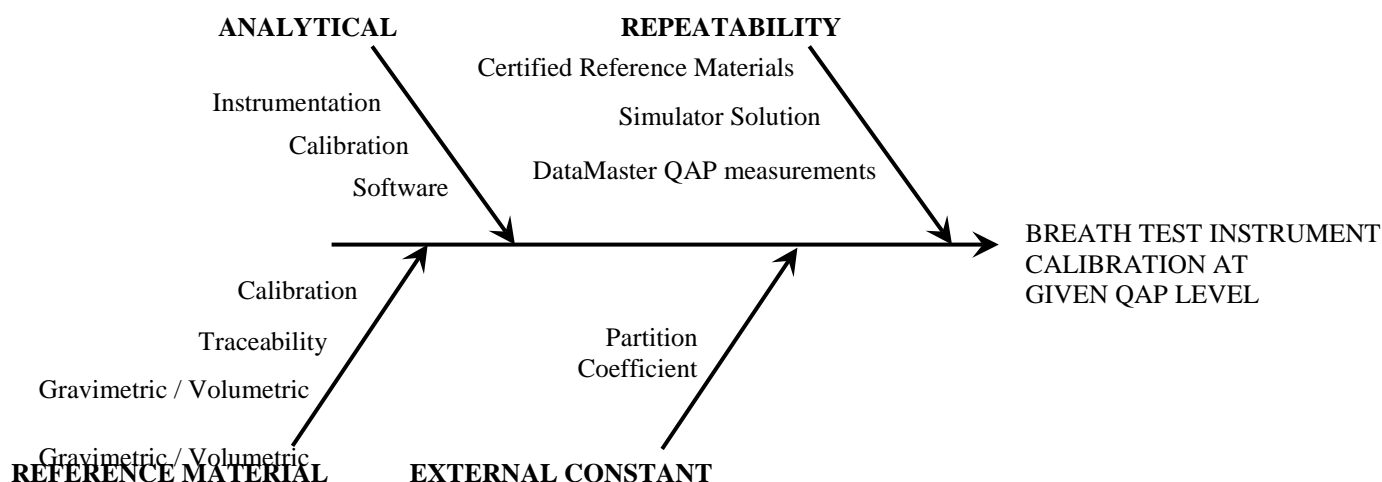


Figure 2: Cause and effect diagram for the calibration of the breath alcohol measuring instrument

## 16.3 MEASUREMENT UNCERTAINTY OF BREATH ALCOHOL CALIBRATION REFERENCE MATERIALS

### 16.3.1 UNCERTAINTY OF ETHANOL REFERENCE MATERIAL VALUE

Multiple ethanol reference materials are measured alongside a simulator solution during certification. The reference materials contain ethanol at a reference concentration which is reported, along with the reference value's uncertainty, in the manufacturer's Certificate of Analysis (COA) for the material. The reference material uncertainty is derived from its preparation by gravimetric and volumetric means and it includes the uncertainty in its analysis against a calibration curve generated using NIST certified reference materials. The gravimetric preparation of the reference material inherently contains uncertainty associated with the equipment used in the weighing, its calibration and the reference standards used in the process.

The COA for the 0.100 g/100 mL ethanol control analyzed after each set of 5 simulator solution replicates is used to source this uncertainty. The COA lists the relative (%), expanded uncertainty for the material ( $k=2$ , 95.45% confidence level). This is converted to the absolute, standard uncertainty through the following equation.

$$CV_{CoA}^2 = \left( \frac{u_{RM}}{1000 / 0.100} \right)^2$$

where:

$CV_{CoA}^2$  = the uncertainty in the value of the reference material

$u_{RM}$  = the relative standard uncertainty of the reference material from the COA

### 16.3.2 UNCERTAINTY FROM REPEATABILITY MEASUREMENTS (SIMULATOR SOLUTION)

Variations in repeated measurements of the simulator solution are derived under reproducibility conditions. These conditions consist of multiple factors including: the analyst, the headspace instrument calibration, instrument operation, environmental conditions, solution sampling and software calculations against the calibration curve. The variations in these results include uncertainty contributions from each of these factors.

This variability is represented through calculation of the relative standard deviation, or percent coefficient of variation, of the simulator solution concentration. First the average solution concentration is calculated using the following equation.

$$\bar{X} = \frac{1}{n} \sum_{i=1}^n X_i$$

where:

- $\bar{X}$  = the average simulator solution concentration
- $n$  = the number of measurements (e.g. 40 for external standard solutions, 15 for QAP solutions)
- $X_i$  = each individual simulator solution measurement result
- $i$  = incremental measurement results, first through last

The standard deviation (SD) of the simulator solution measurements is calculated using the following equation.

$$SD = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n - 1}}$$

The uncertainty from repeatability measurements of an external standard solution ( $CV_{ESS}^2$ ) is calculated using the following equation.

$$CV_{ESS}^2 = \left(\frac{SD}{\bar{X}}\right)^2$$

The uncertainty from repeatability measurements of a QAP solution ( $CV_{QAP}^2$ ) is calculated using the following equation. The standard deviation of the mean of 15 measurements is used in this equation.

$$CV_{QAP}^2 = \left(\frac{SD}{\sqrt{15}/\bar{X}}\right)^2$$

### 16.3.3 UNCERTAINTY FROM REPEATABILITY MEASUREMENTS (REFERENCE MATERIAL)

Variations in repeated measurements of the ethanol reference material are produced from the same uncertainty sources described above. The uncertainty for reference material repeatability ( $CV_{Control}^2$ ) is calculated for external standard solution certification using the following equation.

$$CV_{Control}^2 = \left(\frac{SD}{\bar{X}}\right)^2$$

The uncertainty for the reference material repeatability ( $CV_{Control}^2$ ) is calculated for QAP solution certification using the following equation.

$$CV_{Control}^2 = \left(\frac{SD}{\sqrt{3}/\bar{X}}\right)^2$$

### 16.3.4 UNCERTAINTY FROM INEXACT VALUES OF CONSTANTS

The uncertainty associated with the constant used to convert ethanol solution concentrations (g/100 mL) to ethanol vapor concentrations (g/210 L) is determined from fitting data to the exponential model describing the relationship between the water/air

partition coefficient and temperature. The uncertainty for this constant ( $CV_{Part\ Coef}^2$ ) is calculated using the following equation.

$$CV_{Part\ Coef}^2 = \left( \frac{0.0124}{1.23} \right)^2$$

#### 16.3.5 COMBINED UNCERTAINTY FOR THE EXTERNAL STANDARD SOLUTION

The combined standard uncertainty of the external standard solution ( $u_{ESS}$ ) is calculated using the following equation.

$$u_{ESS} = EVC \times \sqrt{CV_{CoA}^2 + CV_{ESS}^2 + CV_{Control}^2 + CV_{Part\ Coef}^2}$$

where:

$EVC$  = equivalent vapor concentration of the solution

This calculation is done using the spreadsheet application, ESS Test Report Calculation Record. The expanded uncertainty for the external standard solution is obtained through multiplication by a coverage factor (k) of 2 which is equivalent to a 95.45% confidence level. The expanded uncertainty of the external standard solution is reported on the External Standard Solution Test Report with this confidence level.

#### 16.3.6 COMBINED UNCERTAINTY FOR THE QAP SOLUTION

The combined standard uncertainty of a QAP solution ( $u_{QAP}$ ) is calculated using the following equation.

$$u_{QAP} = EVC \times \sqrt{CV_{CoA}^2 + CV_{QAP}^2 + CV_{Control}^2 + CV_{Part\ Coef}^2}$$

This calculation is done using the spreadsheet application, QAP Test Report Calculation Record. An expanded uncertainty is reported for each QAP solution on the Quality Assurance Procedure Solution Test Report, and as such the uncertainty on this record can be understood to have a coverage factor (k) of 2 which is equivalent to a 95.45% confidence level. However, the combined standard uncertainty (k=1) for the QAP solution is used directly in uncertainty calculations related to the instrument calibration and for use in any subsequent breath alcohol test uncertainty calculations. The combined standard uncertainty (k=1) is calculated by dividing the expanded standard uncertainty (k=2) by a factor of 2.

### 16.4 MEASUREMENT UNCERTAINTY OF INSTRUMENT CALIBRATION

#### 16.4.1 UNCERTAINTY FROM REPEATABILITY MEASUREMENTS OF QAP SOLUTIONS ON THE DATAMASTER/DATAMASTER CDM AND DRAEGER ALCOTEST 9510

The variability in repeated measurements of the QAP solution during instrument calibration comes from a combination of instrumental, software and simulator uncertainty sources. This uncertainty from repeatability measurements on the instrument ( $CV_{BTI}^2$ ) is calculated using the following equations:

For the DataMaster, where ten samples are analyzed for each linearity concentration,

$$CV_{BTI}^2 = \left( \frac{SD}{\sqrt{10}} / \bar{X} \right)^2$$

For the Draeger Alcotest 9510, where five samplings are analyzed for each linearity concentration,

$$CV_{BTI}^2 = \left( \frac{SD}{\sqrt{5}} / \bar{X} \right)^2$$

Each of the four calibration concentration levels has an associated  $CV_{BTI}^2$  uncertainty component.

## 16.5 COMBINED UNCERTAINTY FOR THE INSTRUMENT CALIBRATION

The uncertainty sources for the QAP solutions and the uncertainty from repeatability measurements of these solutions on the breath alcohol measuring instrument are combined for the uncertainty of the instrument calibration ( $u_{DM}$ ).

$$u_{BTI} = \sqrt{CV_{CoA}^2 + CV_{QAP}^2 + CV_{Control}^2 + CV_{Part\ Coef}^2 + CV_{BTI}^2}$$

The calculation is done when the Technician has entered all of the applicable data into the Calibration Certificate. The instrument calibration uncertainty is calculated at each of the four QAP levels and expanded uncertainties are produced for each with a coverage factor (k) of 2 which is equivalent to a 95.45% confidence interval. Technical and administrative review of these uncertainty calculations is performed and documented on the Calibration Certificate by the reviewer signing as the "Technician Reviewing and Issuing Certificate".

## 17 LIST OF CHANGES – TECHNICAL MANUAL HISTORY

Since Revision (10/10/11 of TLDCalTM)

Section and Comments	Date Approved	Author/Reviewer
<p>Overall Text and Format</p> <p>Changed title page. Reformatted header and footer. Changed chapter numbers where relevant. Removed most procedures relating to reference material calibration functions. New document ID BTPCalTM. TLDCalTM revised and remains in use for TLD.</p> <p>Replaced Chapter 2 with procedure for receipt and storage of simulator solutions only. Deleted Chapters 3, 4 and 9 entirely.</p>	October 15, 2012	Black/Sharpe
<p><b>Rev. #1</b> Removed language from 1.2.24, added language to 2.2 (solution handling and transport) and to Chapter 3 (equipment ID and handling, acceptance criteria for breath test after certification).</p>	March 15, 2013	Black/Sharpe
<p><b>Rev. #2</b> Removed “Calibration” from Manual Title. Introduced new chapter (4) for the Draeger Alcotest 9510 QAP. Added dry gas handling to chapter 2 and new chapter 6. Where appropriate changed references to DataMaster to “breath test instrument”. Added chapter on barometer certification (14). Consolidated definitions. Changed Uncertainty of</p>	October 30, 2014	Neilson, Denton, Villanti/Sharpe, Couper



Measurement to Measurement Uncertainty. Added formula for calculating Draeger instrument uncertainty (17.4)		
<b>Rev. #3</b>  Removed handheld barometer references. Added procedures to have reference barometer to be submitted to an approved vendor for annual certification.	November 2014	Villanti/Sharpe/Neilson/Couper
<b>Rev. #4</b>  2.1 Policy  This change reflects the shift from internally prepared ESS and QAP solution to solutions prepared by an external vendor. The language was also updated for the dry gas standard to match the ESS and QAP solutions.  <i>2.2.5 Added information about cylinder receipt and storage.</i>  2.2.6 Struck "Not for use in Calibration" from being allowed for use when marking expired solution.  2.2.7 Changed the reference from batch to lot concerning cylinder markings.  3.1 Clarified Conditions Requiring the QAP (DataMaster)  3.2-INSTRUMENT ASSESSMENT  This changes the language for the "As Found" test for both the Draeger and the Datamaser so that the requirements for both instruments are the same.  3.3.8-PERFORM A	July 2016	Mosley/Neilson/Sharpe

<p>DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE.</p> <p>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The k=1 procedure is no longer necessary. The Cal Cert is also being updated to reflect this update.</p> <p>3.3.9 DataMaster test document shall be preserved by photocopy. Once it's checked for accuracy and legibility the photocopy becomes the original. Carbon copies are not kept.</p> <p>3.3.10 The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all data generated, which includes a date, have been initialed.</p> <p>3.4 QAP Review and Certificate Issuance</p> <p>These changes are for the purposes of using the same wording throughout the entire document.</p> <p>4.1 Clarified Conditions Requiring the QAP (Draeger)</p> <p>4.2 Instrument Assessment Modifies the "As Found" procedures for the Draeger and Datamaster so that they are the same.</p> <p>4.3 Procedure (Draeger)</p> <p>Clarifies which version is used.</p> <p>4.3.1-Barometric Pressure Adjustment</p> <p>The change from millibars to</p>		
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<p>Hectopascals mirrors the language the Draeger uses in their documentation and literature. Step four reflects the fact that the barometric pressure only needs to be verified when no adjustment is needed.</p> <p>4.3.2. Calibration Procedure</p> <p>Step B. accurately reflects the procedure.</p> <p>4.3.6 and 4.3.7 were swapped to match the Draeger order.</p> <p>4.3.8 QAP Printout (Draeger)</p> <p>Clarified technicians shall include all produced documents, including the 'as found' printout.</p> <p>4.3.9 Calibration Certificate</p> <p>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The k=1 procedure is no longer necessary. The Cal Cert is also being updated to reflect this update.</p> <p>4.3.10 Added: The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all the data generated, which includes a date, have been initialed.</p> <p>4.4 QAP Review and Certificate Issuance (Draeger)</p> <p>Second paragraph third and fourth sentences added: <i>summary – technician reviewing and issuing calibration certificate will verify "Software Verified" has been written, all documents are included, and match the calibration certificate. See 4.3 above for reason.</i></p>		
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<p>10.4 DataMaster Helps</p> <p>10.4.1 Policy</p> <p>INTERFERENCE DETECTED <i>Change: removed implied consent for blood and added request search warrant for blood.</i> Reason law changed under U.S. v McNeely</p> <p>PUMP Error Added run test again then if fails put out of service.</p>		
<p><b>Rev#005</b></p> <p>2.1 Policy</p> <p><i>This change reflects the shift from internally prepared ESS and QAP solution to solutions prepared by an external vendor. The language was also updated for the dry gas standard to match the ESS and QAP solutions.</i></p> <p>3.2-INSTRUMENT ASSESSMENT</p> <p><i>This changes the language for the "As Found" test for both the Draeger and the DataMaster so that the requirements for both instruments are the same.</i></p> <p>3.3.8-PERFORM A DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE.</p> <p><i>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The Cal Cert is also being updated to reflect this update.</i></p> <p>3.3.9 <i>This change reflects an ASCLD/LAB requirement that thermal paper documents, or documents that degrade be</i></p>		

<p><i>retained in manner where degradation isn't a concern.</i></p> <p>3.3.10 <i>This change is an addition to meet ISO supplemental 4.13.1.1.1</i></p> <p>3.4-QAP REVIEW AND CERTIFICATE ISSUANCE</p> <p><i>These changes are for the purposes of using the same wording throughout the entire document. Breath test document replaces, instrument printout, copies of instrument printouts, and photocopied instrument printouts.</i></p> <p>4.2-Instrument Assessment</p> <p><i>This change mirrors the change to 3.2 and modifies the "As Found" procedures for the Draeger and Datamaster so that they are the same.</i></p> <p>4.3-PROCEDURE</p> <p><i>The Draeger provides the ability to print the current software. Switching to this procedure will provide proof that the software is verified and it will provide a cleaner document for the QAP.</i></p> <p>4.3.1-Barometric Pressure Adjustment</p> <p><i>The change from millibars to Hectopascals mirrors the language the Draeger uses in their documentation and literature. Step four reflects the fact that the barometric pressure only needs to be verified when no adjustment is needed.</i></p> <p>4.3.2 Calibration Procedure</p> <p>Step B. accurately reflects the procedure.</p> <p>4.3.5 Perform the Mouth</p>		
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<p>Alcohol/Invalid Sample Test</p> <p>A. Select the “INVALID SAMPLE TEST” from the menu on the instrument and follow the procedures provided by the instrument.</p> <p>B. A human subject is to exhale into the instrument during the PLEASE BLOW phase shortly after introducing into the mouth a substance containing ethyl alcohol (i.e., mouthwash, beverage alcohol, etc.).</p> <p>C. Verify that the instrument displays “INVALID SAMPLE”.</p> <p>D. Ensure the “INVALID SAMPLE” box is checked on the display screen for the QAP upon completion of the test.</p> <p><i>4.3.6 and 4.3.7 were swapped to match the Draeger order.</i></p> <p>4.3.9 Calibration Certificate</p> <p>A. The Draeger 9510 Calibration Certificate shall be filled out when the above steps have been successfully performed as described. The certificate will be transferred for technical and administrative review as described in the Review and Certificate Issuance section.</p> <p>B. The results of the certification procedure will be examined to ensure they comply with the stated tolerances of accuracy (%bias) and precision (%CV).</p> <p>C. The entire QAP shall be repeated if, during the QAP the Technician is required to replace any parts or components.</p> <p>D. The Expanded Uncertainty value (k=2) listed on the QAP Solution Test Report must be divided by a factor of two. This is automatically computed by the Calibration Certificate when</p>		
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<p>documented in the appropriate column for the Combined Standard Uncertainty.</p> <p>The Cal Cert has been updated to reflect this change.</p> <p>4.3.10 The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all data generated, which includes a date, have been initialed.</p> <p><i>This change is an addition to meet ISO supplemental 4.13.1.1.1</i></p>		
<p>REVISION #6</p> <p>Updated language to reflect merge of ASCLD/LAB into ANAB throughout.</p> <p>Refined language throughout to be more concise.</p> <p>Chapter 1 – Definitions added, terms changed to match current ASCLD/LAB and ANAB terminology</p> <p>Chapter 2 – Changes reflect the BTP taking over ESS and QAP distribution. Clarification of External standard receipt process and use of approved vendors.</p> <p>Chapter 3 - Clarified QAP procedures for DataMaster</p> <p>3.1 Changed order of conditions requiring a QAP.</p> <p>3.2 Allowed use of simulator solution for the “as found” procedure.</p> <p>3.3 Clarified that reason for restarting a QAP will be noted in comments section.</p>	<p>October 2017</p>	<p>Couper/Sharpe/Jones/Neilson/ Dearmore/Maier/Divis</p>

<p>3.3.2 Language updated to reflect ANAB ASCLD/LAB terminology.</p> <p>3.3.3 language changed to reflect ANAB ASCLD/LAB terminology and a note was added to remind techs to use a separate QAP batch for the adjustment and calibration and changed combined uncertainty language.</p> <p>3.3.4 Complete breath test now also referred to as "verification".</p> <p>3.3.9-14 formatting change</p> <p>3.3.8 change reflects using the start of the diagnostic test as the end time of the QAP, which is the current practice</p> <p>3.3.9 Clarified new order that Calibration Certificates will be transferred for reviews and to IDS for final retention.</p> <p>3.4 updated to reflect changes in the way QAP certificates and technical/administrative reviewers are completed</p> <p>3.5 ESS change added to clarify what is required (also addressed in solution change chapter)</p> <p>Chapter 4 - Clarified QAP procedures for Draeger</p> <p>4.1 format change</p> <p>4.2 ANAB language change</p> <p>4.3 Internal printer to print current software, then deactivate internal printer</p> <p>4.3.1 Update procedure to exit the screen</p> <p>4.3.2 reflects the requirement for separate batch numbers for the adjustment and calibration</p>		
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4.3.4 Same requirement as 4.3.2		
4.3.7 Procedure clarifications		
4.3.9 Update current review policies and expanded uncertainty method		
4.3.10 the language was changed to reflect the new certificate issue/tech review process		
4.4 Updated the order of the reviews and issuing certificates		
4.5 Reminder to ensure most current LCB location codes added		
Chapter 5 - Clarified when solution change is performed on Datamaster instruments. Stated how often to update codes.		
5.2 ANAB terminology updates		
5.4 solution change update		
5.6 Cannabis term and timetable		
Chapter 6 - Clarified External Standard Changing details for Draeger		
6.2 ANAB terminology updates		
6.5 Changed to use COA concentration		
Chapter 7 ANAB terminology updates and punctuation		
Chapter 8 - Clarified PBT Certification Protocol to instruct use of altitude chart or correction factor		
8.1 ANAB terminology updates		
8.2 Use of altitude chart		
8.4 Use of Chart and ANAB		

terminology updates		
8.5 ANAB terminology updates		
8.6 ANAB terminology updates		
Chapter 9		
9.1 Use of clear language to eliminate variability		
9.2 Claification of words for uniformity		
Chapter 10 - Added Draeger Help Sheet		
Chapter 11		
11.3 ANAB terminology updates		
Chapter 12		
12.3 ANAB terminology updates		
Chapter 13 - Added when to verify thermometers for accuracy; send digital thermometer to Guth when unacceptable results		
13.1 Clarification for tracking		
13.2 We do not calibrate digital thermometers and ANAB terminology updates		
Chapter 14		
14.2 ANAB terminology updates		
14.3 ANAB terminology updates		
Chapter 15 - Turn off printer when conducting complete breath test.		
15.2G removed to reflect new QAP process		
Chapter 16 – Proficiency Testing Removed		